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PhD thesis

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Achilles tendon rupture: Tendon elongation, gait dynamics, and individualized treatment

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LIST OF PAPERS

Study 1

Reliability of the Copenhagen Achilles Length Measure (CALM) on patients with an Achilles tendon rupture

Hansen MS, Kristensen MT, Budolfsen T, Ellegaard K, Hölmich P, Barfod KW.

Knee Surg Sports Traumatol Arthrosc. 2020;28(1):281–90.

Study 2

The Achilles Tendon Length Measure and the Achilles Tendon Resting Angle show acceptable construct validity using the Copenhagen Achilles Length Measure as gold standard

Hansen MS, Kristensen MT, Hölmich P, Barfod KW.

Foot Ankle Surg. 2021;27(6):655–9.

Study 3

Achilles tendon gait dynamics after rupture: A three-armed randomized controlled trial comparing an individualized treatment algorithm vs. operative or non-operative treatment.

Hansen MS, Bencke J, Kristensen MT, Hölmich P, Kallemose T, Barfod KW.

Submitted manuscript

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- **Hansen MS**, Vestermark MT, Hölmich P, Kristensen MT, Barfod KW. Individualized treatment for acute Achilles tendon rupture based on the Copenhagen Achilles Rupture Treatment Algorithm (CARTA): A study protocol for a multicenter randomized controlled trial. Trials. 2020:12;21:399.

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- Cramer A, **Hansen MS**, Hölmich P, Barfod KW. Neither heel-rise Height (HRH) nor Achilles tendon resting angle (ATRA) show strong correlations to patient limitations and return to previous activities one year after acute Achilles tendon rupture. Foot Ankle Surg 2021. 2021 Nov 21;S1268-7731(21)00217-4.

- Barfod KW, **Hansen MS,** Sandholdt H, Boesen A, Hölmich P, Troelsen A, et al. The Copenhagen Achilles Length Measurement performed at time of acute Achilles tendon rupture is correlated to tendon elongation after one year. J Foot Ankle Surg. 2022 Feb 1;

ABBREVIATIONS

ATLM	Achilles Tendon Length Measure
ATRA	Achilles Tendon Resting Angle
ATRS	Achilles tendon Total Rupture Score
CALM	Copenhagen Achilles Length Measure
CARTA	Copenhagen Achilles Rupture Treatment Algorithm
DADB	Danish Achilles tendon database
EFOV	Extended field of view
ICC	Intraclass correlation Coefficient
MDC	Minimal Detectable Change
MRI	Magnetic Resonance Imaging
PROM	Patient-Reported Outcome Measure
RCT	Randomized controlled trial
SEM	Standard Error of the Measurement
US	Ultrasound
3D	Three-dimensional

ENGLISH SUMMARY

Background: Approximately five persons get injured with an Achilles tendon rupture every day in Denmark, and many of the patients have persisting functional deficits. A common problem after injury is elongation of the healed tendon, which is correlated with decreased muscle strength and function. Though, how to best measure tendon elongation is unclear. Furthermore, the clinical criteria for recommending operative treatment differ and are not evidence based why an individualized treatment selection protocol has been requested.

Purpose: The overall aims of this PhD was to evaluate the reliability and validity of outcome measures used to evaluate tendon elongation and to investigate the effect of an individualized treatment algorithm on the patients' gait dynamics and tendon elongation within the first year after an Achilles tendon rupture.

Methods: In *Study 1*, the reliability of Copenhagen Achilles Length Measure (CALM), an ultrasound examination of tendon elongation, was investigated. In *Study 2*, the construct validity of two indirect measures for tendon elongation (Achilles Tendon Resting Angle, ATRA, and Achilles Tendon Length Measure, ATLM) was investigated using CALM as the gold standard. In *Study 3*, the effect of an individualized treatment algorithm (Copenhagen Achilles Rupture Treatment Algorithm, CARTA) on gait dynamics and tendon elongation was investigated in a three-armed randomized controlled trial.

Results: *Study 1* found excellent inter-rater relative reliability of CALM (ICC $\geq$ 0.75). Measurement error on a group level ranged between 0.3-0.6 cm (18-29 SEM%) and on an individual level between 0.8-1.7 cm (47-81 MDC%). *Study 2* found a linear relationship between ATRA, ATLM and CALM, which were statistically significant in all models ($p<0.01$). *Study 3* found no statistically significant differences between the intervention group in comparison with the control groups. Among the intervention group, compared with the un-injured leg, the injured leg had decreased peak ankle plantarflexor moment (6%, $p=0.039$) and peak ankle plantarflexor power during pushoff (14%, $p=<0.001$) at 6 months. The moment was restored at 12 months, but the power was still reduced (with 7%, $p=<0.027$). Tendon elongation was also significant at 6 (17.7 mm, $p=<0.001$) and 12 months (19.4 mm, $p=<0.001$).

Conclusion: CALM had excellent reliability, but a quite large measurement error. Both ATRA and ATLM showed acceptable construct validity for assessing tendon elongation after rupture. Patients given individualized treatment using CARTA did not have better gait dynamics or less tendon elongation than patients treated as usual.

DANISH SUMMARY/DANSK RESUMÉ

Baggrund: Omkring 5 personer kommer til skade med en akillesseneruptur hver dag i Danmark og mange af patienterne får vedvarende funktionelle begrænsninger. Et hyppigt problem efter skaden er at senen heler op i forlænget position hvilket er korreleret med nedsat muskelstyrke og funktion. Dog er det uklart, hvordan man bedst måler seneforlængelsen. Ydermere, er de kliniske kriterier for hvornår operativ behandling bør anbefales meget forskellige og ikke baseret på evidens hvorfor individualiseret behandlings beslutning er bleven efterspurgt.

Formål: De overordnede formål med denne PhD var at evaluere reliabilitet og validitet ved målemetoder som bruges til at evaluere seneforlængelse og at undersøge effekten af en individualiseret behandlingsalgoritme i henhold til patienternes gangdynamik og seneforlængelse det første år efter en akillesseneruptur.

Metode: S*tudie 1* undersøgte reliabiliteten af Copenhagen Achilles Length Measure (CALM), som er en ultralydsundersøgelse. I *studie 2* blev construct validiteten af to indirekte mål for seneforlængelse (Achilles Tendon Resting Angle, ATRA og Achilles Tendon Length Measure, ATLM) testet med CALM som golden standard. I *studie 3* blev effekten af en individualiseret behandlingsalgoritme (Copenhagen Achilles Rupture Treatment Algorithm, CARTA) undersøgt i henhold til gangdynamik og seneforlængelse i et tre-armet randomiseret kontrolleret studie.

Resultater: *Studie 1* viste fremragende inter-bedømmer reliabilitet for CALM (ICC $\geq$ 0.75). Målefejlen på gruppeniveau varierede mellem 0.3-0.6 cm (18-29 SEM%) og på gruppeniveau mellem 0.8-1.7 cm (47-81 MDC%). *Studie 2* viste en lineær sammenhæng mellem ATRA, ATLM og CALM, hvilket var signifikant i alle modeller ($p<0.01$). *Studie 3* viste ingen statistisk signifikante forskelle mellem interventionsgruppen sammenlignet med kontrolgrupperne. Bland interventions gruppen, ved sammenligning med ikke-skadet ben, havde det skadede ben nedsat maks ankel plantarflexor moment (6%, p=0.039) og maks ankel plantarflexions power ved afsæt (14%, p=<0.001) ved 6 måneder. Kraftmomentet var genvundet ved 12 måneder, men power var fortsat nedsat (med 7%, p=<0.027). Seneforlængelsen var også signifikant ved 6 (17.7 mm, p=<0.001) og 12 måneder (19.4 mm, p=<0.001).

Konklusion: CALM havde fremragende reliabilitet, på trods af relativt store målefejl. Både ATRA og ATLM viste at have acceptabel construct validitet for måling af seneforlængelse efter ruptur. Patienter som modtog individualiseret behandlingsvalg baseret på CARTA viste ikke fordele i henhold til gangdynamik eller seneforlængelse sammenlignet med patienter behandlet som vanligt.

INTRODUCTION

Basics about the Achilles tendon

Structure

The Achilles tendon is the thickest and strongest tendon in the human body (1).
The average length of the Achilles tendon is 15 cm (ranges from 11 to 26 cm) (1), and the thickness of the tendon is approximately 0.4-0.5 cm (2,3).

The Achilles tendon begins near the middle of the calf and is the conjoined tendon of the triceps surae (1) (Figure 1). The three-headed triceps surae consists of the gastrocnemius (superficial with a medial and a lateral head) and the soleus muscle (the profound head) (1).

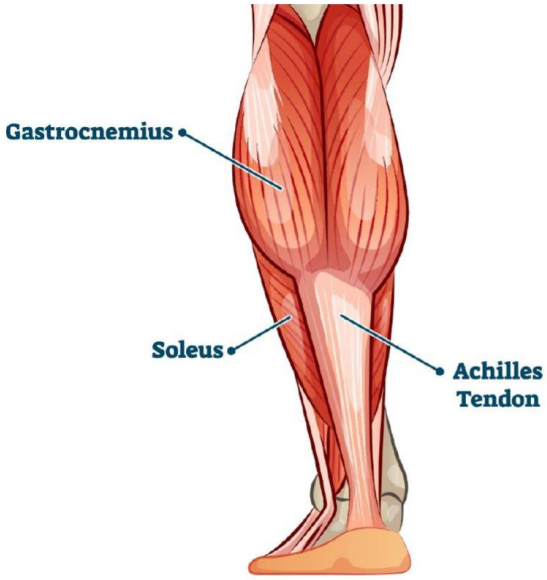


Figure 1. The anatomy of the Achilles tendon and the triceps surae muscle, conjoined in the Achilles tendon. *Illustration: Colourbox*

Proximal, the Achilles tendon begins at the musculotendinous junction of the gastrocnemius and soleus being flattened. It becomes rounded approximately 4 cm from the calcaneus where the tendon inserts (4). As fibers proceed distally, they rotate 90 degrees such that the fibers that lie medially in the proximal portion become posterior distally. This structure contributes to the elastic recoil within the tendon (5).

The composition of the Achilles tendon is built by paralleled bundles of Type 1 collagen. These fibers are organized into fibrils and assume a wavy pattern. Microfibrils are grouped into fibrils. Fibrils are organized into fibers. A group of fibers is then organized into fascicles grouped into bundles (4). The fascicles are surrounded by connective tissue to form the structure of the tendon, covered by the epitenon that is further surrounded by the paratenon. A layer of fluid reduces friction during tendon movement between the layers (6).

Mechanism

Tendons have almost perfect mechanical properties for the transmission of force from muscle to bone. Tendons are stiff and strong, stretching up to 4 percent before damage (1). The collagen fibrils are crimped when the tendon is at rest, giving them a wavy structure. When the tendon gets loaded, it causes tensile stress, and the fibrils are stretched. If the stretch on the tendon remains less than 4 percent, the fibers regain their original structure to remove the load. At stretch levels between 4 and 8 percent, the fibers start to slide past one other if there is more than 8 percent of strain, the tendon ruptures (5).

Achilles tendon rupture; who, when, and how

The incidence of an Achilles tendon rupture is 31-35 per 100.000/year (7), which can be translated to approximately 2000 persons getting injured every year in Denmark or five persons every day.

Who

Based on data from the 2021's report from the Danish Achilles tendon database (DADB) (8,9), the typical patient with an Achilles tendon rupture is male (relationship male-female is 4:1) around 50 years of age (SD 14.4). If dividing all patients into age groups (<30, 30-50, 50-70, >70), the largest incidence is within the 30-50 years group. Epidemiological studies have previously presented an average age of approximately 42-43 years of age (10,11). The DADB data, including five times as many patients (3228 patients) (8) as the epidemiological studies mentioned above (528 and 718 patients) (10,11), could be an explanation for this difference.

Comorbidities that might influence tendon healing registered in DADB were high blood pressure (17%), arthritis (3.5%), and diabetes (4.1%). One out of five patients (22%) had experienced problems with the Achilles tendon prior to their injury (8).

When

Most patients are injured when performing sports (5). The most common sports registered in DADB are listed in Figure 2 (8).

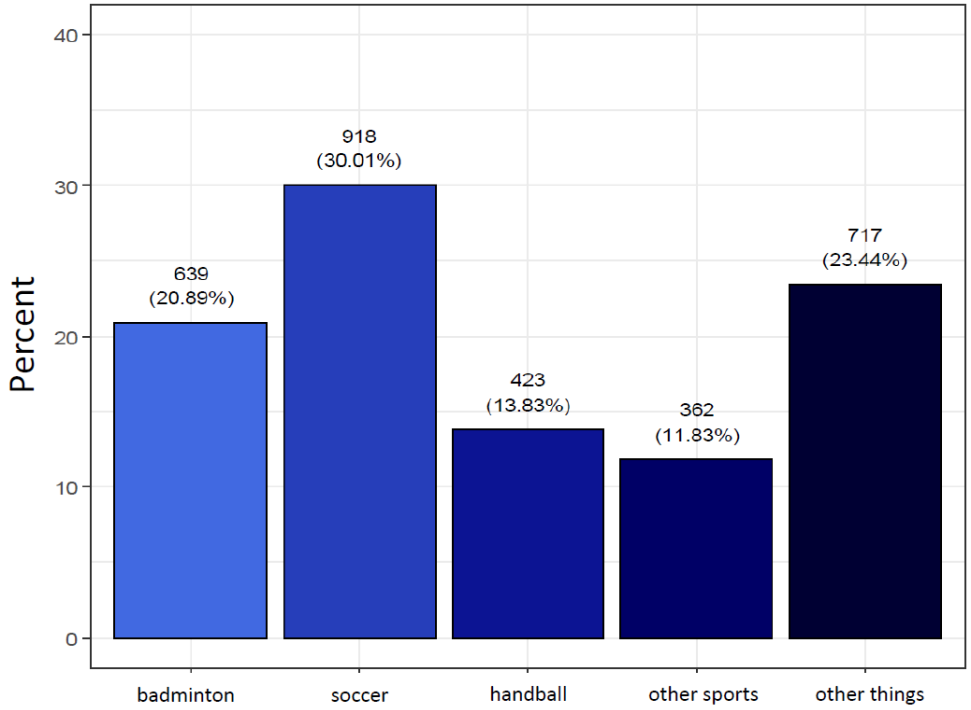


Figure 2. What the patients were doing when their tendon ruptured (n=3059) (8).

The term "weekend warrior" has been used to describe middle-aged patients participating in sports more or less frequently (12). This phenomenon can be confirmed by the data in DADB, where 41% of the patients got injured when conducting an activity that is rarely performed (maximum four times a year). Out of these patients, 57% were injured while conducting a sport that the patients have performed previously in their life (8).

The seasonal variation of incidence with an Achilles tendon rupture has been presented, with the spring having the highest incidence (13). On the contrary, a Danish registry study showed the highest incidence in the fall, with a peak in September and the least common in the summer (7). For the Danish people, this data could be explained by the start of all major sports after the summer holidays (7).

How

Three main categories have been described considering the trauma resulting in an Achilles tendon rupture: 1) Pushing off with the weight-bearing forefoot while extending the knee. This result is often seen in sprint starts and jumping sports like basketball. 2) Sudden, unexpected dorsiflexion of the ankle. This injury can occur when the foot slips into a hole. 3) Violent dorsiflexion of a plantarflexed foot, which may occur after a fall from a height (5).

One of the big questions still unanswered is why the Achilles tendon ruptures. The etiology is probably multifactorial and includes local-, biomechanical-, histological-, medication- and genetic factors (14).

Diagnosis

The patient with an acute Achilles tendon rupture often describes a sudden pain and a snap in the back of the calf. Sometimes together with a snapping sound. Many patients experience a feeling of being kicked from behind, for example, in a soccer game, but when looking behind, no one was behind them. Clinically, the patients are often (but not always) unable to push off during walking or to conduct a heel raise (15). During palpation of the calf and the Achilles tendon, a gap is often revealed at the rupture site, most often 2-6 cm above calcaneus (5) (Figure 3).

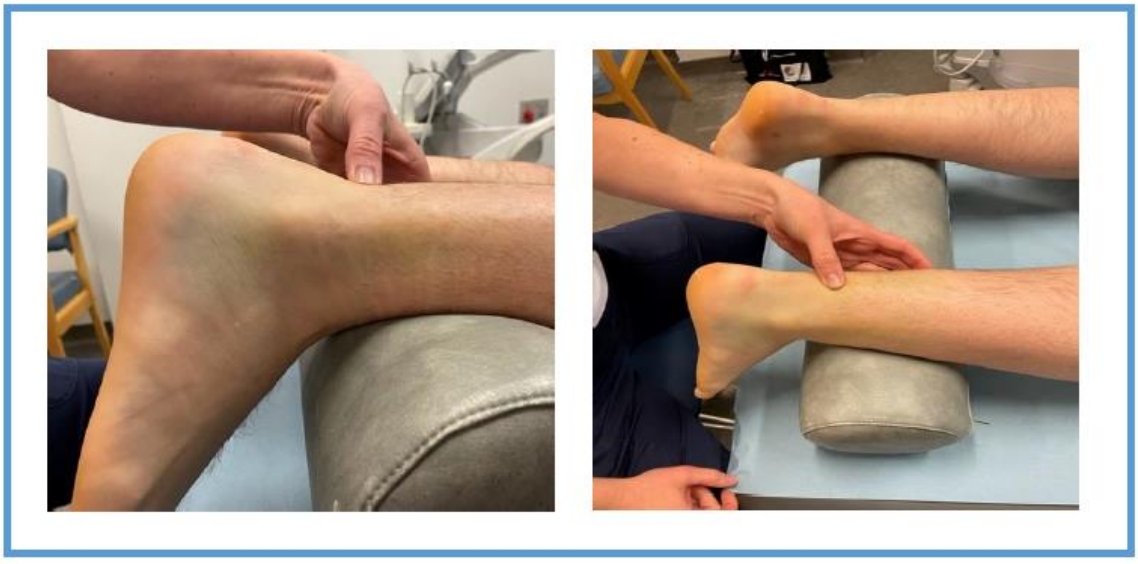


Figure 3. A patient with an Achilles tendon rupture 6-7 cm above calcaneus with a palpable gap.

Two clinical tests have shown to be reliable to diagnose an Achilles tendon rupture (15); the Matles test (16) and Thomsons test (17) (Figure 4). Both are easy and quick to perform. Within both tests, the patient lays prone. The Thomsons test, also called the calf squeeze test, is

performed with the patient lying with both feet hanging free outside the examination table. The tester squeezes the calf, and the response on an un-injured leg is a small plantarflexion of the foot. The absence of plantarflexion is a positive test (17). The Matles test is performed with the patient laying with both knees flexed 90 degrees and relaxing in the ankle joints. The test is positive if the injured foot is hanging down in a dorsiflexed position compared to the un-injured foot (16). The Matles test was used clinically in a modified way to evaluate tendon elongation during the rehabilitation phase. If the foot on the injured limb was hanging in increased dorsiflexion, the tendon was evaluated to be elongated. Using the modified Matles test was subjective and difficult especially if several persons followed the same patient over time.

The use of Magnetic Resonance Imaging (MRI) and ultrasound (US) in diagnostic aims is not necessary. It is recommended to rely on the clinical tests and use these modalities if additional information is needed (18).

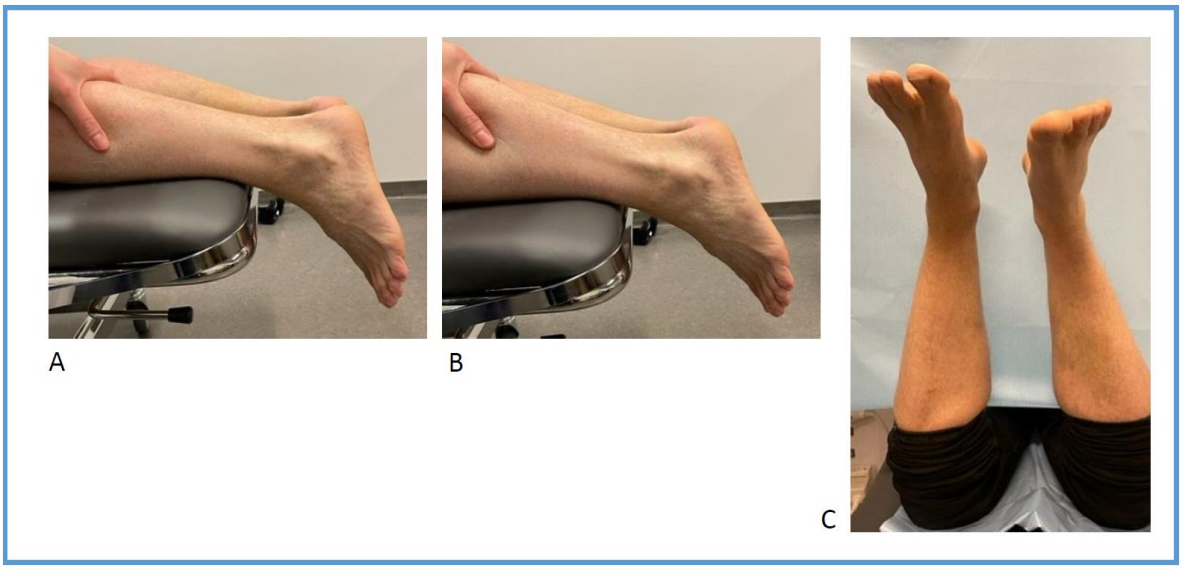


Figure 4. A) Thomsons test start position, B) Thomsons test when squeezing the calf, a plantar flexion of the ankle joint arises, the test is negative (no rupture), C) a positive Matles test on the right side since the foot is hanging down in a dorsiflexed position (the Achilles tendon is ruptured).

Treatment of an Achilles tendon rupture

Operative treatment

Operative treatment has traditionally been the treatment choice in Orthopaedic departments in most Scandinavian countries (19). The surgery can be conducted either open or minimally invasive. This surgery is followed by treatment with a cast and/or a brace (Figure 5). Typically for 6-8 weeks in total. The degree of allowed weight-bearing and movement in the ankle joint varies in the cast/brace period. Rehabilitation exercises follow the period in a cast/bandage and, if relevant, training to return to sport (20,21).

Figure 5. A patient with a cast (A) and a patient with a brace (B). With the cast, it is not possible to weight bear, which it is while wearing a brace. The heel wedges (C) are placed in the brace, allowing the ankle joint to be placed in a plantar flexed position.

Non-operative treatment

The evidence (22–24) and clinical practice (7) have shifted towards non-operative treatment during the last decade. This treatment takes advantage of the inflammatory process that automatically starts when injured and getting a hematoma. A granuloma is formed, and collagen is produced, which gradually increases its mechanical strength so that loading can lead to elastic deformation. The production of collagen type 1 takes over, and the callus reaches its largest size. The collagen is resorbed and replaced by remodeling to produce better structure and cross-linking (25). The non-operative treatment has similar principles as the operative treatment with 6-8 weeks in a cast/brace followed by rehabilitation.

Which treatment is the best?

Current evidence does not point out operative or non-operative treatment superior to the other. The many RCT studies produced in recent years have been analyzed in several meta-analyses (26–29), concluding the same; there are pros and cons with both treatment modalities. In short, they conclude a significant reduction of re-ruptures (26–29) in the operative group but, on the contrary, a significantly higher rate of other complications (26,28,29).

How to make the difficult choice

Deciding who is better treated operatively and who will have a satisfactory result with the non-operative treatment is not always easy and the evidence is deficient. Traditionally, clinicians have spoken for the advantages of operative treatment for the younger patient who also have high demands for physical function. At the same time, recommended avoiding the operative treatment to the patients who potentially could have problems with healing due to comorbidities (5). Ochen et al. (29) point out, "The final decision on management of acute Achilles tendon ruptures should be based on patient-specific factors and shared decision making."

Two studies have presented a rationale for individual treatment selection (30,31). Ten years ago, Amlang et al. (30) presented an ultrasonographic classification of Achilles tendon ruptures. The technique needed to conduct this examination was thorough, but there was no follow-up or evaluation after classifying the patients. A couple of years later, Hutchison et al. (31) presented their management program where ultrasound findings strongly influenced the choice of treatment. However, they did not have a control group and a questionable follow-up (no valid functional outcome and a quite large follow-up loss).

Inspired by Amlang et al. (30), Barfod et al. developed the Copenhagen Achilles Rupture Treatment Algorithm (CARTA) (32). Based on Amlangs considerations and by evaluating the correlation between Amlangs classification and Copenhagen Achilles Length Measure (CALM) and tendon elongation at one year, the CARTA was developed. CALM is an ultrasound (US) based examination to measure tendon elongation after rupture (CALM is described in detail in the "Outcomes" section, page 34). CARTA includes an ultrasound examination in two parts; evaluation of tendon overlap and CALM (Figure 6):

- *Tendon overlap:* In a transverse view on the US machine, if less than 25% tendon fibers at the rupture site, the overlap is considered minimal, and the patient is selected for operative treatment. If more than 25% fibers, the overlap is considered substantial. The treatment decision will be based on the next scan.

- *CALM:* After examination of both legs with CALM, the differences between them are calculated as the elongation and was given in percent of the length of the non-injured tendon. If an elongation up to 7%, the patient is treated non-operative. If an elongation at 7% or more, the patient is treated operative. A thorough description of the US examinations is described in the protocol paper (20).

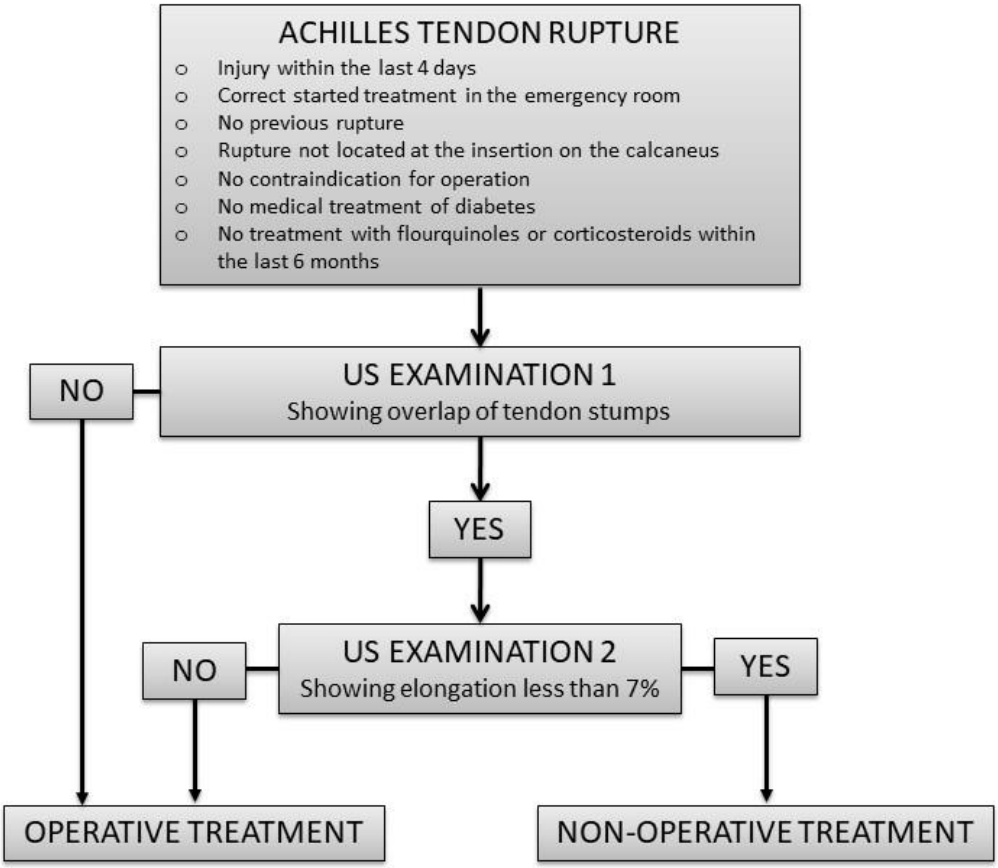


Figure 6. The Copenhagen Achilles Rupture Treatment Algorithm (CARTA) includes two ultrasonographic (US) investigations.

CALM at baseline has shown a statistically significant correlation to CALM at one year (32). An acceptable tendon elongation at 7% was determined using a ROC analysis where elongation at one year was not to exceed 10%. The optimal cutoff, tendon elongation of 7% at baseline, gave a sensitivity of 0.77 and specificity of 0.50 for predicting 10% elongation at one year. Moreover, 77% of the patients that would end up with an elongation above 10% at one year would be identified and therefore be recommended to be treated operatively. Nevertheless, for patients selected for non-operative treatment, one out of two would end up with an elongation above 10% (32).

A three-armed randomized controlled multicenter trial is ongoing at the moment aiming to evaluate CARTA (20). The primary outcome is the heel-rise work test, and 300 patients will be included. Study 3 in this thesis evaluates the first 60 patients included at one of the participating hospitals.

To our knowledge, CARTA is the only treatment algorithm including a valid and reliable measurement (CALM) and being evaluated in a randomized set-up (20).

Deficits after an Achilles tendon rupture

An Achilles tendon rupture has many consequences for the individual patient, which persists for a long time (33–35). Loss of muscle strength (33,34,36,37), decreased level of physical activity (38,39), affected gait dynamics and running pattern (35,40,41), the ability to hop and jump (22,35) are deficits frequently reported in the literature. Also, some studies have enlightened some of the psychological aspects of getting injured with an Achilles tendon rupture, such as fear of movement (39,42,43). The deficits being investigated in this PhD are described below.

Tendon elongation

An outcome frequently studied in the last decade is elongation of the ruptured Achilles tendon. It has been proposed that a longer Achilles tendon may explain a persistent plantar flexion strength deficit (44). Furthermore, Achilles tendon elongation also seems to correlate with clinical outcome score; less elongation gave a better outcome score (45) and a longer Achilles tendon requiring increased muscle activation for gait (46). An explanation for this could be patients healed with an elongated Achilles tendon accompanied by the remodeling of musculus triceps surae to shorter muscle fascicles and a decrease in muscle mass (47).

Elongation has been reported among operatively (45,48,49), and non-operatively (50,51) treated patients. To our knowledge, only two randomized controlled studies have investigated if tendon elongation differs between the treatment groups. The results showed no significant between-group differences for one of the studies (50) and less elongation among the operative treated group for the other study (19 mm longer ($p<0.001$) tendons in patients treated non-operative measured with MRI) (52). The explanation of why the tendon gets elongated is not settled. It is probably numerous, influenced by surgical techniques and materials (45) and progressive tendon elongation afterward (53).

Diniz et al. (54) presented a review in 2020. They questioned whether tendon elongation is a problem since they concluded fair evidence of its effect on functional strength and patient-reported outcome measures. However, they also point out differences in how tendon elongation is measured as a source for discrepancies in the clinical relevance of Achilles tendon elongation.

Additionally, the different methods for measuring tendon elongation confuse the reporting of results. Basically, measurements of tendon elongation can be divided into four groups: radiographic markers (45,50), MRI (44,55), US (55,56), and indirect measurements (51,57) (using the resting position of the foot as a surrogate measure). These four groups can subsequently be divided into two groups depending on how the tendon elongation is measured and calculated:

- *Separation of the tendon ends:* The method used with the radiographic markers. The implanted markers measured radiographically can only measure the change in distance of the tissue between the markers over time and not between anatomical landmarks. Since the markers are implanted after the tendon ruptures, they cannot illustrate the elongation.
- *Tendon elongation:* The method used for all the other length measurements. They measure the distance between anatomical landmarks and use the non-injured sides tendon as a reference. The tendon elongation can therefore be measured over time and from the time at rupture and at any time point.

Gait dynamics

Gait dynamics have been seen to be affected both short (58,59) and long term (35,40,41) after an Achilles tendon rupture.

In a follow-up study where patients treated non-operatively were assessed 4.5 years after injury, they found increased peak dorsiflexion (2 degrees) in the ankle joint during gait in the injured leg compared to the un-injured leg accompanied by decreased total positive plantarflexor work for the injured leg (40). These results align with those presented among a follow-up of non-operative treated patients, two-five years after injury (41). They also showed reduced muscle work on the injured side compared to the non-injured side.

Aufwerber et al. (59) analyzed gait eight weeks and six months post-operative to compare gait recovery in patients treated with early functional mobilization or standard treatment using three-dimensional (3D) gait analysis. They conclude that the early functional mobilization did not lead to a more symmetrical gait pattern. All patients describe significant differences between injured

and non-injured sides at eight weeks, closer to normal at six months. For the early functional mobilization group, a decreased peak ankle power and peak plantarflexion moment were present on the injured side compared to the non-injured side six months after surgery.

Furthermore, the power in the plantarflexor muscles in the ankle during push off, which represents the end-range plantar flexion, is thought to be reduced due to an elongated tendon (60,61). This implies shortened muscle fibers at the given plantar flexion angle (60). Therefore, the ankle plantarflexor power during push off is a biomechanical outcome of high relevance.

Patient-reported outcome measure

The deficits objectively described above are also seen in the subjective measurement with patient-reported outcome measures (PROM). In a systematic review where PROMs for patients with an Achilles tendon rupture were investigated, they concluded the Achilles tendon Total Rupture Score (ATRS) to be the most appropriate outcome measure to use (62).

ATRS is frequently used, and the results presented differ widely. When using ATRS in research studies, the mean value at 12 months has been around 80-90 points (37,38,63). In DADB (8), where all patients with an Achilles tendon rupture are included, the mean point at 12 months is 57 points (2106 patients), and at two years, 64 points (1489 patients) (Figure 7). If the large discrepancies in total scores between DADB and published research studies is due to differences in sample sizes, cultural perception of the score, selection bias within research studies or a mere expression of outcome is unclear.

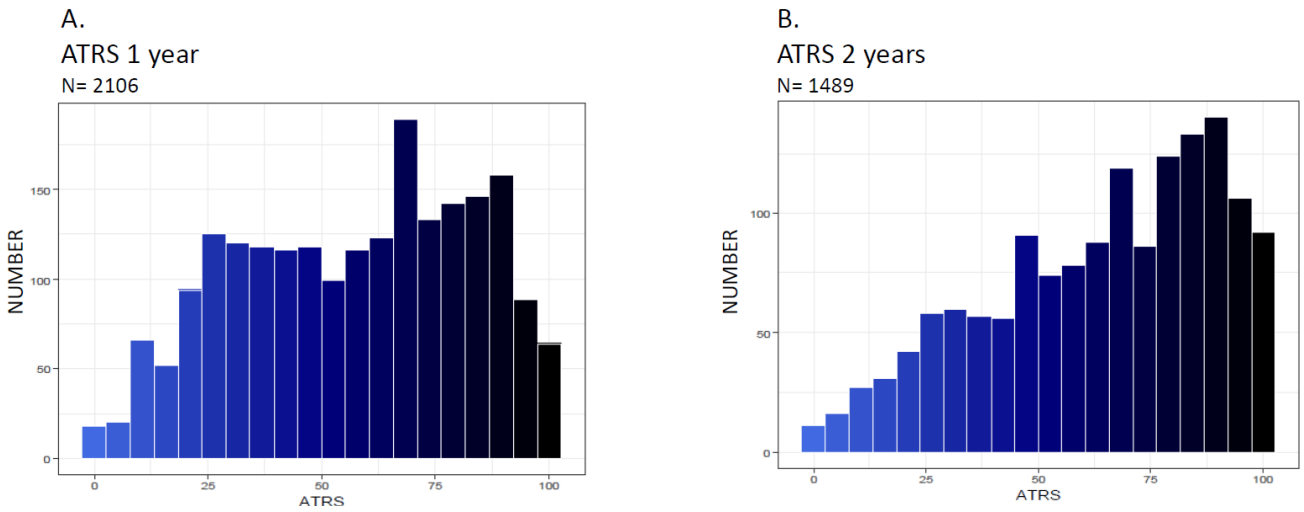


Figure 7. The mean score of the Achilles tendon Total Rupture Score in DADB at 1-year (A) and 2 (B) years (8).

Reliability and validity of outcome measures

Reliability

Reliability can be conceptualized as reproducibility or dependability (64). Quantifying reliability and interpretation of the results are surprisingly unclear in the medical literature in general, probably since reliability can be assessed in various contexts and concepts (65).

Reliability can be divided into relative and absolute reliability. Relative reliability refers to the extend different persons keep their results in a situation of repeated measures (66) which for continuous data most often is evaluated with the Intraclass correlation coefficient (ICC) with a correlation coefficient ranging between -1 to +1 (63). The ICC is calculated based on an analysis of variance. Therefore, it reflects degrees of correlation and agreement among ratings (64,66). There are three overall models of ICC; One-way random effects (each subject is measured by a different set of randomly selected raters), two-way random (raters are randomly selected and each subject is measured by the same set of raters), two-way mixed (fixed raters are defined) (66).

Fleiss' classification can be used (67) to interpret the ICC values. An ICC above 0.75 indicates excellent reliability, between 0.40 and 0.75 as fair to good reliability and below 0.40 as poor reliability.

Absolute reliability reflects to what degree repeated measure varies among individuals and is expressed in the same unit as the measurement. The absolute reliability gives information about to which extent a change of the results is due to variation within the measurement and when a real change is seen (66). Standard error of measurement (SEM) and minimal detectable change (MDC) is derived from a reliability coefficient, often the ICC. SEM indicates the smallest change needed to indicate a real change beyond the measurement error on a group level, while MDC indicates a real change required for one single person (68). Comparing the measurement error of the two tests between different scales, the SEM% and MDC% can also be calculated (69). How SEM and MDC are calculated is shown in Figure 8.

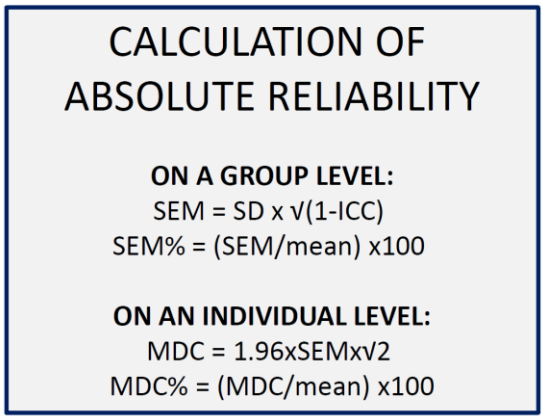


Figure 8. The calculation of absolute reliability, on the group and individual level (70,71). *SD* and *mean* used in Study 1 was; *SD* of the cumulative mean of both raters' measurement from all subjects and *mean* the cumulative mean for both raters' measurement.
Abbreviations: SEM, Standard error of measurement; SD, Standard deviation; ICC, intraclass correlation coefficient; MDC, Minimal detectable change.

The terms reliability and agreement are often used in the same way even though they conceptually are different (72). One definition is: "Reliability can be defined as the ability of a measurement to differentiate between subjects or objects. On the other hand, the agreement is the degree to which scores or ratings are identical" (72).

The Bland-Altman plot describes the agreement between two quantitative measurements (73). It is a method developed to quantify the agreement between two quantitative measurements by constructing limits of agreement. These limits are calculated using the mean and the standard deviation of the differences between the two measurements. A graphical approach is used to check the assumptions of normality of differences, resulting in a scatter plot XY. The Y-axis shows the difference between the two paired measurements, and the X-axis represents the average of these measures. Meaning the difference between the two paired measurements is plotted against the mean of the two measurements. Bland-Altman recommended that 95% of the data points lie within ± 2SDs of the mean difference (73).

Validity

Validity refers to how well a measuring tool measures what it is intended to measure. Validity can be divided into content validity, face validity, construct validity, and criterion validity (74):

Content validity: Is whether or not the measure used is representative for the functions trying to be measured (66).

Face validity: Is to what extend an outcome measure seem to measure what it is attended to measure (66).

Construct validity: Reflects the ability of an instrument to measure an abstract concept or construct (64).

Criterion validity: Is to what extend the results from an outcome measure is correlated with an existing measure seen as the gold standard (66).

The focus of this thesis is the construct validity. The reason for not using a test of correlation (R2) which typically is done when investigating the validity against a gold standard, is that ATLM and ATRA are indirect measurements of tendon elongation and not directly concurrent to CALM. Therefore, when using a direct measure of tendon elongation as the gold standard (CALM), it seemed more relevant to investigate if ATRA and ATLM measure the same construct as CALM and thereby to see if they are associated to each other.

Status of reliability and validity on outcome measures for elongation in 2017

The " Methods " section presents the outcome measures being evaluated for reliability and validity in this thesis (page 32). To better understand the base and need for these studies, the status of reliability and validity at the start of this PhD is presented in Table 1.

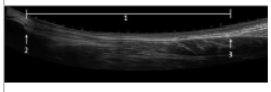
Name of measurement	Measures	Developped Year	Reliability test	Validity test
ATLM 	Indirect measure of tendon elongation Distance from foot to underlay	2014	Only for injured and non-injured side and not for elongation (difference between sides)	No
ATRA 	Indirect measure of tendon elongation Degree of resting angle in the ankle joint	2013	Only for injured and non-injured side and not for elongation (difference between sides)	No
CALM 	Direct measure of tendon elongation	2013	Yes, but only on non-injured persons	Yes

Table 1. Status of reliability and validity of ATLM, ATRA, and CALM in 2017. Abbreviations: ATLM, Achilles Tendon Length Measure; ATRA, Achilles Tendon Resting Angle; CALM, Copenhagen Achilles Length Measure.

OBJECTIVE OF PHD THESIS

The overall aims of this PhD thesis was to evaluate the reliability and validity of outcome measures used to evaluate tendon elongation and to investigate the effect of an individualized treatment algorithm on the patients' gait dynamics and tendon elongation within the first year after an Achilles tendon rupture.

Aims of the studies

Study 1

To examine the relative and absolute reliability of CALM at the time of rupture and at 2, 4- and 12-months post-rupture in patients with an Achilles tendon rupture.

The secondary aim was to investigate the relative and absolute reliability of measurements of tendon elongation measured with ATRA and ATLM.

Study 2

To examine the construct validity of ATLM and ATRA using CALM as gold standard among patients treated non-surgically after an Achilles tendon rupture.

Study 3

To investigate if gait dynamics, Achilles tendon elongation, and patient-reported outcome measure differ between patients using the individualized treatment algorithm CARTA and patients treated as usual (operative or non-operative by default).

PATIENTS AND METHODS

Study designs, patients, materials, ethical considerations

In the following chapter an overview of the research methods applied in the thesis is provided. A discussion of methodological considerations is done in the end of this chapter. For detailed descriptions, see the full papers 1-3 in the appendix. The following text is based partly on text from paper 1-3 to ensure methodological consistency and transparency. Care has been taken to avoid self-plagiarism as defined by the Graduate School of Health and Medical Science, University of Copenhagen.

Study 1

Study design

This study was performed as a cross-sectional study where the reliability for CALM was measured during four time points the first year after injury. ATRA and ATLM were measured at two times points after injury.

Patients

Two groups of patients were included in this study. Group A (56 patients) was included to examine the reliability of CALM. Group B (28 patients) were included in a previous study (51) and was used to examine the reliability of ATRA and ATLM.

Inclusion criteria for both groups were: minimum 18 years of age, diagnosed with an Achilles tendon rupture within the last five days, able to speak and understand Danish. Exclusion criteria: previous Achilles tendon rupture or operation on the Achilles tendon, rupture within 1 cm from the calcaneus, treatment with fluoroquinolone or cortisone within the last six months, arterial insufficiency in the legs, terminal or a critical medical illness.

Patients treated both operative and non-operative were included. They all followed the same rehabilitation protocol: a cast in maximal equinus position for the first two weeks and a DJO Aircast Walker from Weeks 3-8.

Material: set up for intra- and inter-rater testing

The patients in group A (CALM) were measured at four times: 0-4 days after injury and at 2, 4- and 12-months post-rupture by two raters. Rater A started all test sessions, followed by rater B,

and lastly, rater A finished the session. The raters were blinded to each other and their own measurements.

The patients in group B (ATRA and ATLM) were measured at 8- and 16-weeks post-rupture. At eight weeks, intra and inter-rater testing was performed, and at 16 weeks, only intra-rater. The testers were blinded to each other's and their own ratings.

Ethical considerations

The patients received oral and written information before written consent was obtained. This study was reported to the Capital Region's Research Ethics Committee, which deemed no approval required.

Study 2

Study design

This study was done as a validity study using prospectively collected data.

Patients

Data from 130 patients from a previous RCT (21) were included.

Inclusion criteria: age 18-70, able to attend follow-up examinations, speak and understand Danish, and written informed consent. Exclusions criteria: previous Achilles tendon rupture or operation in the Achilles tendon, a distance less than 1 cm from the rupture to the calcaneus, treatment with fluoroquinolones, or a cortisone injection within the last six months, arterial insufficiency in the legs, terminal or critical medical illness.

All patients were treated non-operative and followed the same rehabilitation protocol as in Study 1.

Material: testing procedure

ATRA, ATLM and CALM measurements were conducted 2, 4, 6 and 12 months after rupture following the same order every time; ATLM followed by ATRA and lastly CALM.

Ethical considerations

The patients received oral and written information about the project. Permission was obtained from the Ethical Review Board of the Capital Region of Denmark.

Study 3

Study design

This study was an exploratory, three-armed randomized controlled trial.

Patients

Sixty patients were randomized in a 1:1:1 order to one of three groups. The criteria for in- and exclusion are presented in Figure 9.

INCLUSION CRITERIA:

- 18 to 65 years
- an appointment in the outpatient clinic within four days from time of rupture
- a total Achilles tendon rupture
- initial treatment with split plaster cast with the ankle in maximal plantar flexion started within 24 hours from time of rupture
- possibility to attend post-examinations
- ability to speak and understand Danish and to give informed consent

EXCLUSION CRITERIA:

- a rupture of the Achilles tendon either at the insertion on the calcaneus or at the musculotendinous junction
- previous rupture of the Achilles tendon in any of the two legs
- treated with flourquinoles or corticosteroids within the last 6 months
- in medical treatment of diabetes
- other conditions prior to the injury resulting in reduced function of any of the two legs
- contra-indication for surgery
- terminal or severe medical illness

Figure 9. The inclusions and exclusions criteria in Study 3.

Material

- The intervention

The patients randomized to the intervention group were treated according to the individualized treatment algorithm CARTA (20) based on two ultrasonographic examinations. The examinations were conducted within four days after injury, one after the other. CARTA is described in the Introduction (page 19).

- Non-operative treatment

The patients randomized to the intervention group with the decision to be treated non-operative or the non-operative control group were treated with a circular below-the-knee cast with the ankle held at maximal plantar flexion. No weight-bearing is allowed. Three weeks later, the cast

was changed to a functional brace with three heel wedges promoting plantarflexion in the ankle. A wedge was removed after two and four weeks. The orthosis was removed after six weeks. Partial weight-bearing was allowed from week four and full weight-bearing from week eight. In Weeks 10 – 13, the patients were instructed to perform a home exercise program twice daily. From Week 14, the patients started rehabilitation in the municipality (20).

- Operative treatment

The patients randomized to the intervention group with the decision to be treated operatively or the operative control group were operated on within 14 days after injury. The procedure was performed in local anesthesia. The tendon stumps were drawn into the transverse incision, and two modified Kessler sutures were performed to fix the tendon. The ankle was placed in maximal, unforced plantar flexion before the sutures were tightened maximally, bringing the tendon stumps together inside the peritendium. The ankle needed to be in an equinus position, comparable with the un-injured leg after tensioning. The following treatment with cast and orthosis as well as instructions and exercise program was the same as for the non-operative group (20).

Follow-up

All patients were evaluated at baseline (0-4 days after injury) and attended follow-up measurements six and 12-months post injury. Included outcomes are presented in the next chapter.

Ethical considerations

The operative and the non-operative treatment of acute Achilles tendon rupture were well-known treatments at our hospital. The patients enrolled were not subject to any extraordinary inconvenience because both operative and non-operative treatment of acute Achilles tendon rupture were currently standard treatments. We just did not know who would benefit the most from the respective treatment. The study was carried out under the principles of the Helsinki Declaration, and the study was approved by the National Committee on Health Research Ethics. All patients received oral and written information about the trial before written consent was obtained.

Outcomes

Outcomes used in study 1-3 are presented below. An overview of which outcome measure is used when is presented in Table 2.

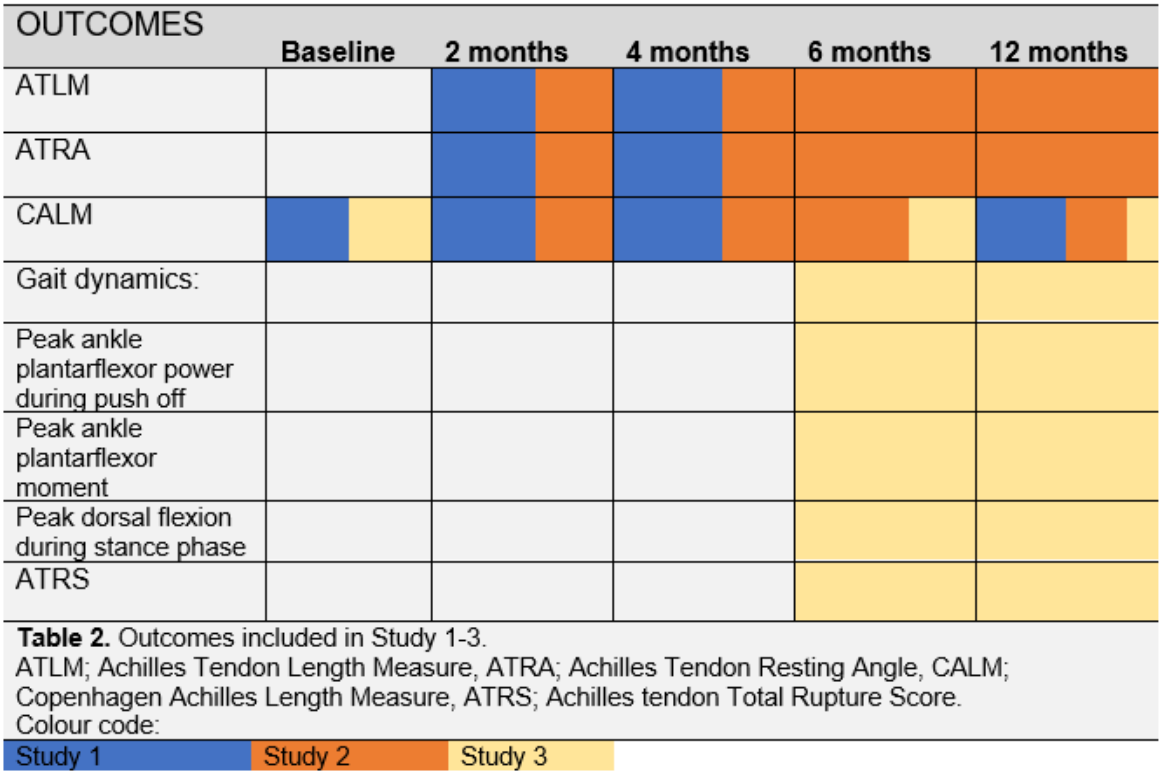


Table 2. Outcomes included in Study 1-3.
ATLM; Achilles Tendon Length Measure, ATRA; Achilles Tendon Resting Angle, CALM; Copenhagen Achilles Length Measure, ATRS; Achilles tendon Total Rupture Score.
Colour code:
Study 1 | Study 2 | Study 3

Tendon elongation

ATLM

ATLM was inspired by the modified Matles test (page 17). The thought behind ATLM was to perform a modified Matles test but to add an objective measure – in this case, a ruler (Figure 10)(51). ATLM is the distance in centimeters between the center of the fifth metatarsal head and the underlay. The patient's position when performing ATLM was the same as for modified Matles, but a wooden plate was placed under the patient's knees to provide a hard surface. The point of reference, the center of the fifth metatarsal head, was marked with a pen. A 100 cm ruler was then placed perpendicular to the plate. The absolute ATLM (the distance for each side) has shown excellent relative and absolute reliability (51). The reliability of relative ATLM (tendon elongation) is investigated in Study 1 (75) and the validity in Study 2 (76).

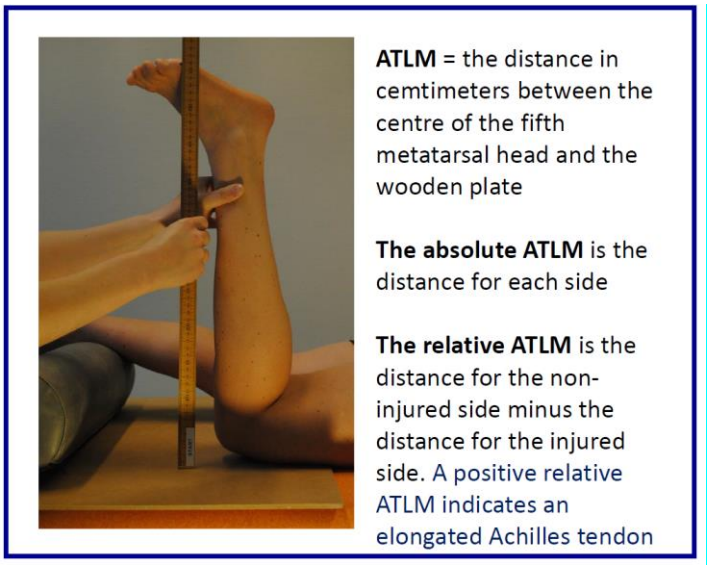


Figure 10. The Achilles Tendon Length Measure (ATLM) is an indirect measure for tendon elongation (51).

ATRA

ATRA was presented by Carmon et al. in 2013 (57), at the same time as we started to develop ATLM (51). ATRA is the pointed angle between the long axis of the fibula, the apex at the tip of the fibula, and the line to the fifth metatarsal head (57). When we were about to evaluate the reliability of ATRA in a previous study (51), we added some details from Carmont's description of how to perform ATRA (57) to improve the reproducibility: reference points of the lower leg were marked with a pen, and a standard 30 cm long-armed goniometer with 1° increments was used. Points of reference: the middle point of the head of the fifth metatarsophalangeal head, the top of the fibula (the lateral malleolus), and the caput fibula (57) (Figure 11).

The absolute ATRA (the resting angle for each side) has shown excellent relative and absolute reliability (51). The reliability of the relative ATRA (tendon elongation) is investigated in Study 1 (75) and the validity in Study 2 (76). Carmont's calculation of relative ATRA is non-injured minus injured sides values (57). In Studies 1 and 2, we have chosen to calculate tendon elongation the other way around to get a positive number instead of a negative (51).

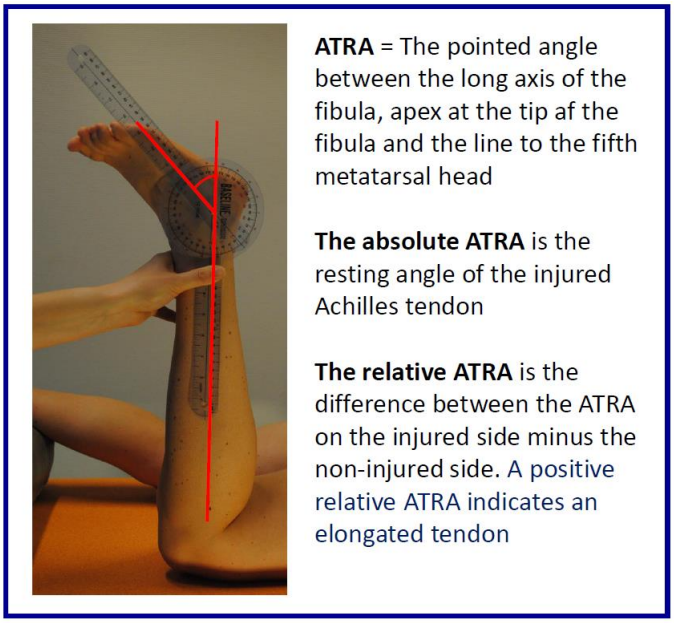


Figure 11. The Achilles Tendon Resting Angle (ATRA) is an indirect measure of tendon elongation (51,57).

CALM

CALM is a measurement of tendon elongation based on a US measurement consisting of two measures of the Achilles tendon: the total length and the free length of the Achilles tendon (55,77). Both measurements use the insertion at the calcaneus as a distal landmark. For the total length of the Achilles tendon, the distal tip of the medial gastrocnemius is used as a proximal landmark (55), and for the free length, the distal tip of the soleus (77). It is the total length that is used in this thesis. The proximal and distal landmark of the Achilles tendon is localized. This measurement is followed by measuring the distance between landmarks with a tape measure (Figure 12).

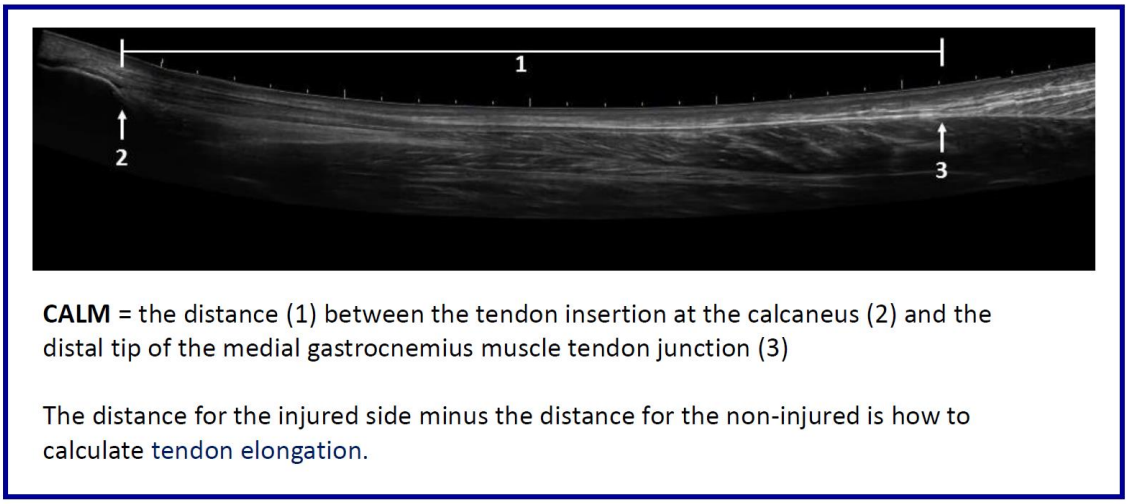


Figure 12. The Copenhagen Achilles Length Measure (CALM) is a direct measure of tendon elongation (55).

The scanning is done with the patient laying prone (Figure 13). The position of the knee and feet differs if used in Studies 1 and 2 or Study 3. In Studies 1 and 2: the knee flexed 10°, a foam pad placed anterior to the ankle joint with the feet resting in a relaxed manner against it. The ankle joint is positioned in 10° of plantar flexion by adjusting the foam pad. Study 3: when using CALM in the CARTA algorithm in the acute phase, the patient is positioned as described above. When using CALM at 6- and 12-months follow-up, the patient was positioned with extended knee and feet hanging relaxed outside the end of the examination table. This adjustment was done since we thought the tendon would be stretched to better reveal the actual length of the tendon. The reason for not using this position in the CARTA was that we wanted to measure the displacement of tendon ends in the position it would heal in during the initial examination.

The landmarks were found by scanning longitudinally. After localizing the landmark, it was centered in the middle of the image with the probe oriented in the sagittal plane. Then a needle was introduced between the probe and the surface of the skin, projecting the landmark to the skin (Figure 13). This point was marked on the skin with a pen. The distance between the landmarks was finally measured with a tape measure (accuracy 1 mm). When investigating healthy individuals, CALM has shown good validity and reliability (55,56). The reliability of CALM when used in patients is tested in Study 1 (75).

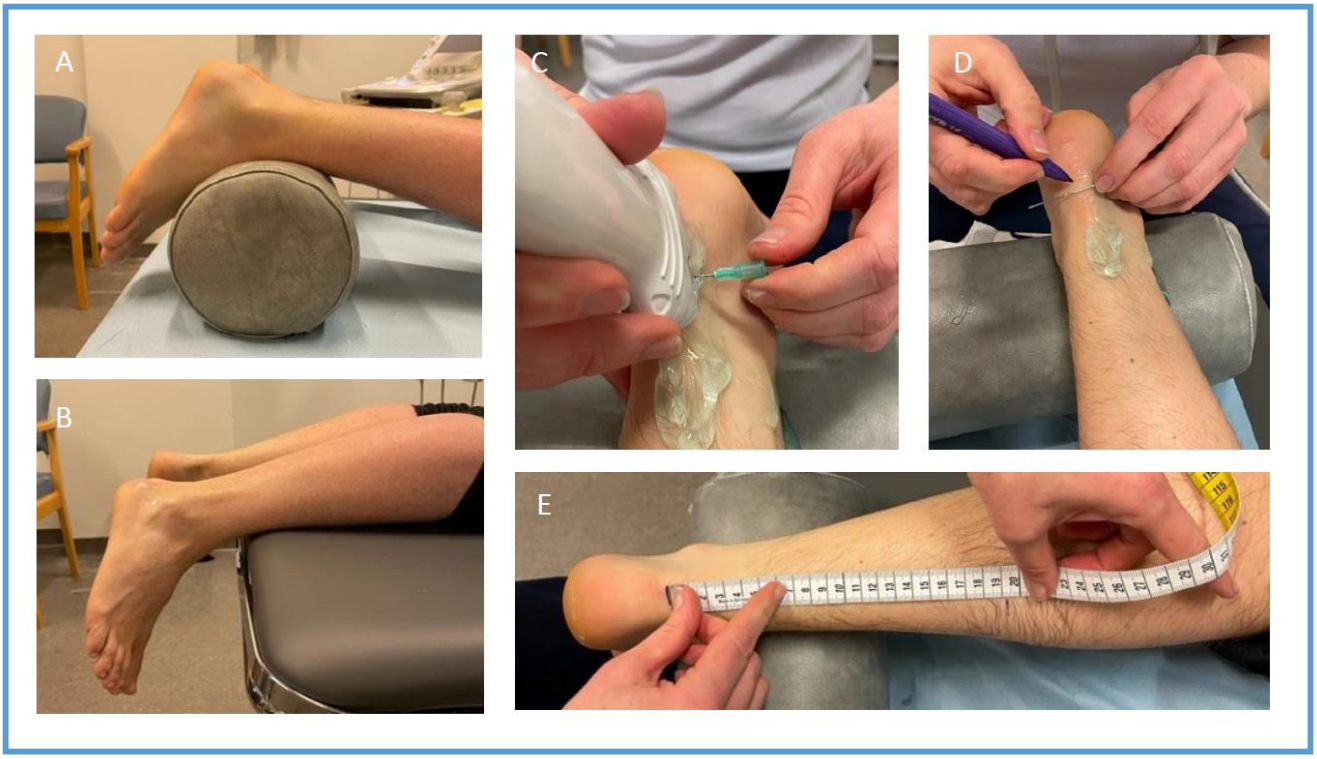


Figure 13. CALM measurement: A) Position of the patient's feet when conducted in the acute phase in Study 3 and Studies 1 and 2, B) position of the patient's feet during when conducting CALM during follow up measurements in Study 3, C) introducing the needle between the probe and the surface of the skin projecting the landmark to the skin, D) marking the landmark on the skin with a removable marker, E) measuring the distance between the landmarks with a tape measure.

At present, there are two methods described to measure tendon elongation with the US. Besides CALM (75), the extended field of view (EFOV) is also described in the literature (2). EFOV is a feature on the US machine adding a series of pictures to form one long picture where both the beginning and the insertion of the Achilles tendon are visible: the musculotendinous junction of the soleus/the gastrocnemius and the calcaneus. After saving the picture, the length measurement is performed using the measurement tool on the US machine. EFOV is has shown to be reliable when used on healthy persons (2), but it has not been tested for reliability on patients with an Achilles tendon rupture.

Gait analysis

Gait analysis is an objective and systematic analysis and description of quantities that characterize human locomotion (78). Gait is a dynamic activity, which can be quantified by kinematic and kinetic measurements (79).

Kinematics

Kinematic data describes movement independent of the forces causing the movement (79). The kinematic outcome used in Study 3 was peak dorsiflexion angle during the stance phase. At the end of the mid-stance in the gait cycle, the ankle reaches peak dorsiflexion around 10-15 degrees (Figure 14) (79).

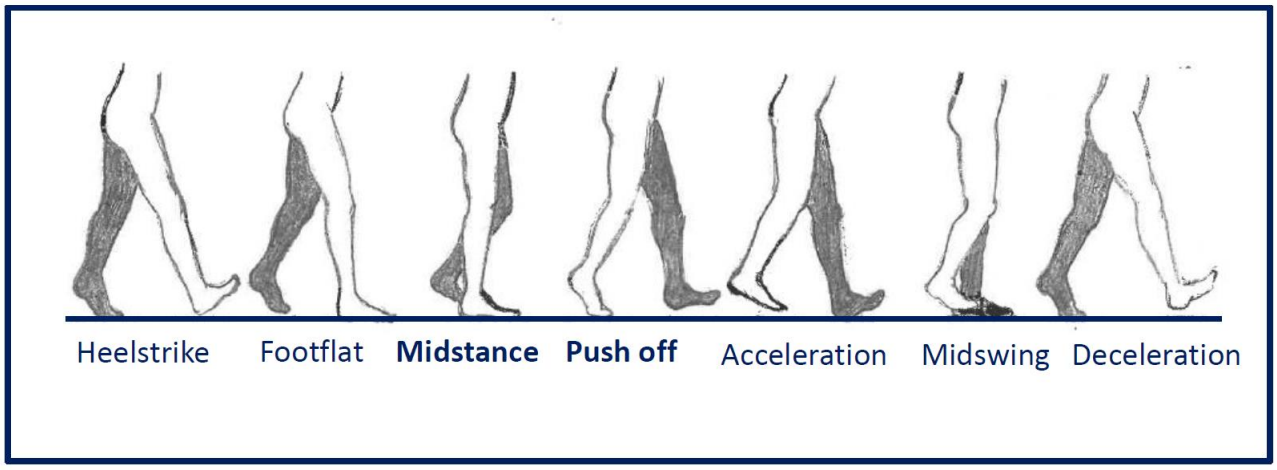


Figure 14. The right leg (white) demonstrates the different phases in the gait cycle in normal gait. The peak dorsiflexion most often occurs at the end of midstance. The peak ankle plantarflexor moment occurs approximately after midstance when push off is initiated. Shortly after, the peak ankle plantarflexor power during push off occurs.

Kinetics

Kinetics are the forces causing the movement, both internal and external. The internal forces are gained from muscle activity and the ligaments, while the external forces occur from external loads or the ground reaction force (80). The kinetic outcomes used in Study 3 were:

- *Peak ankle plantarflexor moment*. A joint moment is the product of the magnitudes of muscle force and the length of the associated muscle moment arm (Figure 15). The moment is measured in the newton meter (79). The peak ankle plantarflexor moment occurs approximately after midstance when push-off is initiated (Figure 14). Generally, since the moment arm is expected to be similar between injured and non-injured sides, the moment could be considered a force in this context. The peak ankle plantarflexor moment is the largest among the plantar flexor moment during the gait cycle.

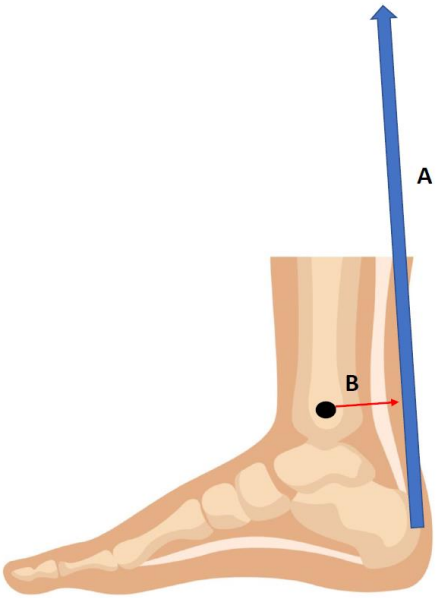


Figure 15. The ankle plantarflexor moment is the product of (A) the force of the plantarflexor musculotendinous complex and the (B) moment arm of the musculotendinous complex.

- *Peak ankle plantarflexor power during push off.* Power combines the magnitude of the moment with the simultaneous angular velocity of the joint (or the speed at which the joint is being flexed or extended). When the joint moment is caused by muscles working concentrically, the muscles generate (positive) power. The unit for power is Watt/kg body mass. The magnitude of power is influenced by the moment's magnitude and the joint angular velocity. For example, low power generation can be seen when the joint moment is significant, but the joint is moving slowly (79). The peak ankle plantarflexor power during push off is the largest amount of power in the push off phase (Figure 14) in the gait cycle.

<u>3D gait analysis</u>

A 3D motion capture system (Vicon Motion Systems) was used in Study 3 to obtain an objective evaluation of the gait performance in 3D. The examination started with anthropometric data (measure leg length, knee width, ankle width, distance between the anterior superior iliac spines) and measuring height and body weight. Before the gait analysis, 22 reflective markers were placed on the skin with double-adhesive tape on specific anatomical locations (Figure 16). The patients were instructed to walk normally barefooted at self-selected speed on a 10-meter walkway. This process was repeated until five gait trials for each leg with complete hits on the force plates were achieved. During the walking trials the reflective markers were recorded by 8

infrared cameras mounted on the walls around the laboratory (T40, Vicon Motion Systems, Oxford, UK). From the 3D positions of the markers, the joint angles during gait were calculated, and, in combination with the ground reaction forces from two force plates embedded in the floor, the joint moments and powers were obtained. Kinematic and kinetic data were calculated using inherent software (Nexus 2.9.1; Vicon Motion Systems, Oxford, UK), and the outcome variables were extracted using a custom-written MATLAB script (MATLAB 9.0.0, R2016; MathWorks Inc., Natick, MA). The mean value of the gait trials for each leg was used for statistical analysis. A systematic review evaluating the reliability of 3D kinematic gait measurements concluded it to have moderate to good reliability for sagittal and coronal plane variables (81).

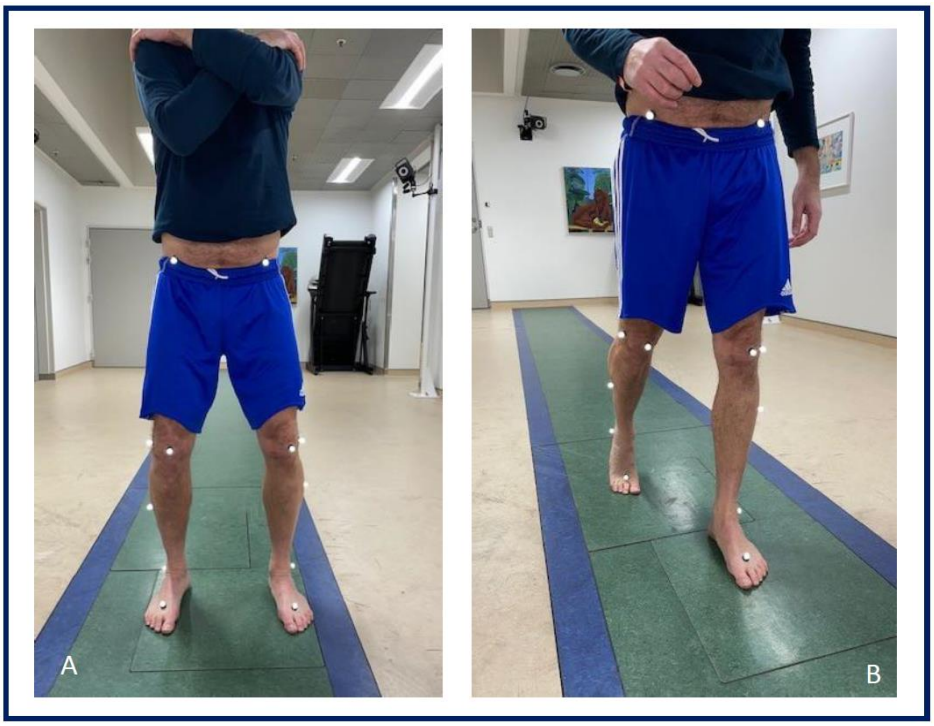


Figure 16. Demonstrates the reflective skin markers in the 3D gait laboratory during the static position (A) and while walking (B), hitting both force plates.

Patient-reported outcome measure

Patient-reported outcome measures (PROMs) are often used to evaluate the effect of treatment, both on an individual level and a group level in research studies. The only evidence-based and patient-specific PROM available is the Achilles tendon Total Rupture Score (ATRS) (82). ATRS consists of 10 questions concerning symptoms and physical activity after an Achilles tendon rupture. The answers range from 0 to 10, where ten is equal to no symptoms/problems (maximum total score = 100). The Danish version was found to have good validity and was reliable for comparison on group level (83). The ATRS in Study 3 was used without the instruction manual (84).

The clinical relevance of the above-mentioned outcome measures has not been established. Only the ATRS has been investigated considering the Patient Acceptable Symptom State (57 points at one year after injury) and Treatment Failure (33 points at one year) as an attempt to define treatment satisfactory (85).

Statistics

The statistical methods used in this thesis are presented in Table 3.

Statistical considerations

Study 1: The $ICC_{2.1}$ model was chosen (two-way random effect model) since it gives the possibility to generalize the results to other raters in similar populations (66).

In a reliability study, it is recommended to assess both the relative and absolute reliability because of limitations within the use of ICC (86); The ICC does not provide an assessment of measurement error, it does not indicate if there is a systemic error and the range of measured values influences the ICC. Higher ranges are associated with higher ICCs independent of actual measurement error (86). Therefore, this reliability test uses both ICC, SEM/MDC, and Bland Altman plots. Further description of the reliability calculation can be read in the Introduction chapter (“Reliability and validity of outcome measures,” pages 24-26).

Study 2: The measurements for ATRA, ATLM, and CALM were longitudinal (measured over time) dependent (the same patients). Moreover, they measured slightly different constructs, and had different scales. This made a direct comparison not possible, but a mixed linear regression model was chosen to investigate how changes on the different scales were associated. Three

models were investigated (dependent/independent); CALM/ATRA, CALM/ATLM, and ATRA/ATLM. The confidence intervals of the estimates were used to evaluate the degree of uncertainty.

Study 3: This study had an exploratory design. When planning the study, no data were available to make a reliable sample size calculation for the primary outcome. The sample size was therefore based on what was logistically possible.

Between group comparisons in the three-armed design was performed by use of ANCOVA to account for possible confounders. ´

The outcomes expressed in power and moment were calculated as the percentual deficit (difference between injured and non-injured side/value for non-injured side*100) to make it easier to understand and interpret the results.

Statistical method	Study 1	Study 2	Study 3
Type of data			
Dichotomous	X	X	X
Continuous	X	X	X
Ordinal, categorical			X
Sample size calculation based on			
Logistical considerations	X		X
Previous collected data		X	
Missing data			
Multiple imputation			X
Comparison between groups			
Paired t-test	X		
ANCOVA (testing intervention group vs. control group)			X
Reliability			
ICC, SEM, MDC, Bland-Altman method	X		
Validity			
Mixed linear regression model		X	

Table 3. An overview of the statistical methods used in the three studies. The significance level was set to 0.05 (two-tailed) for all significance tests.

Methodological considerations

Study 1

Patients

The aim was to include 20 patients at each time point (0-4 days after injury and at 2, 4- and 12-months post-rupture), 80 patients in total. The number of patients included was 56, which potentially has introduced bias. Additionally, not following patients over time but having a cross-sectional design limits the interpretation of development of tendon elongation over time. This demand a follow-up of the same patients over time, which was done in Study 2 and 3.

Raters

Two raters measured all patients and were instructed to follow the manual for conducting CALM. They had been trained by the same senior researcher and clinician who had expertise in US measurements. Still, some degree of bias was expected as the measurement got personalized with time. A way to have limited this kind of bias could have been regular training sessions where the raters measured the same patient together and secured that the protocol was followed.

Rater A was the first to conduct the measurement, followed by rater B. Even though the results for CALM do not imply a case of learning effect of the measurement, a randomized order regarding whom to start the measurement procedure would have been preferred.

Blinding

After marking the landmarks with a pen on the skin, the raters measured the distance between the proksimal and distal landmark with a blank strip of paper. After both raters' measurements were carried out, the paper strips were measured with a tape measure. To measure the distance this way, in two steps, could have intriduced bias. However, the alternative not to blind the raters' results was thought to give a larger degree of bias than the source of error the blinding procedure gave.

Study 2

The gold standard

It can be questioned if CALM was the optimal gold standard for the measurement of elongation. MRI has shown slightly better reliability when measuring non-injured test persons (US: ICC 0.97, SEM 3 mm, MDC 9 mm and MRI: (ICC 0.98, SEM 2 mm and MDC 6 mm) (55) and one could argue that the use of MRI as the gold standard would have been preferred. CALM

measured with US was chosen as the gold standard as the difference to MRI was considered without clinical relevance.

Study 3

Sample size

When planning this study, no valid data were available to use in a sample size calculation. Therefore, the sample size was based on what was logistically possible, which indicates the results to be considered exploratory and not confirmatory. The included sample of 60 patients is larger than previous study populations when investigating gait dynamics (35,40,87) and was realistic for us to conduct. Using another outcome as primary outcome would have allowed the possibility to conduct a sample size calculation and thereby a confirmatory result. Though, the aim of the study was to investigate the effect on an outcome relevant for all patients, gait dynamics. However, a sample size calculation has been performed in the ongoing multicentre RCT (20) which is conducted at the moment, and as such a confirmatory evaluation of CARTA will be addressed.

Blinding

Because of the nature of the intervention, it was not possible to blind the patient. The same physiotherapist that included and randomized the patients conducted the follow-up at 6 and 12 months. Blinding of the physiotherapist at follow-up was attempted. During the gait analysis at follow-up, the patient was instructed not to mention whether she/he had been through surgery or not, and which group they had been randomized to. Also, the patient placed a piece of tape over the Achilles region on the injured leg. Sometimes the patient accidentally mentioned their treatment, and other times, the tape did not cover perfectly. During most follow-up examinations, approximately three out of four times, it did work out well. The last part of the follow-up, the US examination, was not possible to blind due to the scar.

It would have been preferable to have different persons that included the patient and conduct the follow-up, to remove the source of bias.

Set up for rehabilitation

The physiotherapy-led rehabilitation started after the walker was removed at the hospital. The patient was encouraged to continue the rehabilitation subsequently. Most patients participated in rehabilitation offered by their municipality, and some contacted a private physiotherapist. Our hospital collaborates with eleven different municipalities. All collaborating municipalities

participated in a meeting where an example of a “best practice” rehabilitation plan were presented with a concrete exercise program including progression as well as instructions to the patient for the first year after injury. Though, it was impossible to control the treatment the patients were given. On one hand, the diversity of treatment the patients have received might have introduced bias. On the other hand, this setup is how it works in real life, and the results we see give a picture of how it would affect our patients if it were implemented in the clinical practice.

SUMMARY OF RESULTS

In the following chapter a summary of results from the three studies are presented. For detailed description please read the specific papers 1-3 in the appendix.

Study 1

The relative reliability of CALM was found to be excellent (ICC ≥ 0.75) for both intra-rater and inter-rater reliability. Absolute reliability showed a measurement error on a group level for intra-rater between 0.3-0.4 cm (17-19 SEM%) for elongation (difference between injured and non-injured side). Corresponding results for inter-rater reliability were 0.3-0.6 cm (18-29 SEM%). On an individual level, the measurement error for intra-rater was 0.8-1.1 cm (44-52 MDC%) for elongation. Corresponding results for inter-rater reliability was 0.8-1.7 cm (47-81 MDC%). Only a few outliers were observed (above the 95% CI).

Tendon elongation was 2.1 cm (1.4) at the time of rupture and 1.6 cm (0.9) at 12 months.

Relative reliability was excellent for ATRA (ICC ≥ 0.75) and fair to excellent (0.58-0.79) for ATLM. The measurement error on a group level for Intra and inter-rater ranged between 1.1-2.3° (7-14 SEM%) for ATRA and 0.4-0.8 cm (22-28 SEM%) for ATLM. On an individual level, the measurement error ranged between 3.1-6.4° (19-40 MDC%) for ATRA and 1.1-2.2 cm (61-76 MDC%) for ATLM.

Study 2

The regression model demonstrated linear relationships between ATRA, ATLM, and CALM, which were statistically significant in all models ($p<0.01$). For each degree ATRA increased, CALM increased by 0.39 mm (CI 0.12;0.66). For each cm ATLM increased, CALM increased by 1.65 mm (CI 0.65;2.65). For each cm, ATLM increased, ATRA increased by 1.57 degrees (CI 1.26;1.89).

All three measurements showed the largest tendon elongation at the two-month follow-up, which decreased over the first year. Elongation at two months measured with CALM was 20.4 mm (CI 17.2;23.5), with ATRA 14.5˚ (CI 13.3;15.8) and with ATLM 2.8 cm (CI 2.5;3.1). Corresponding values at 12 months were 15.6 mm (CI 12.7;18.5) for CALM, 8.1˚ (CI 7.1;9.1) for ATRA and 1.5 cm (CI 1.3;1.7) for ATLM.

Study 3

One hundred and fifty-six patients were assessed for eligibility. Sixty patients were randomized: 21 patients were allocated to the intervention group and 20 and 19 patients respectively to the two control groups. The use of the CARTA algorithm led to 14 of 21 patients in the intervention group being treated operatively and seven patients non-operatively.

There were no statistically significant differences between the intervention group in comparison with the control groups regarding gait dynamics, tendon elongation, or ATRS six and 12 months after injury. The intention to treat and per protocol analysis did not differ.

For the intervention group, compared to the un-injured leg, the average peak ankle plantar flexor power was significantly lower for the injured leg at six months (14%, p=<0.001) and 7% (p=<0.027) at 12 months. Correspondingly, the peak ankle plantarflexor moment was statistically significantly lower in the injured leg at six months (6%, p=0.039), but not at 12 months (1%, p=0.52). Peak dorsiflexion angle during stance phase was 2.2 degrees (p=0.063) at 6 months and 0.2 (p=0.746) at 12 months. Tendon elongation among the patients in the intervention group was 17.7 mm (p=<0.001) at six months and 19.4 mm (p=<0.001) at 12 months. The total ATRS score at 12 months among the intervention group was 73.6 (63.81:83.33, p=<0.001).

In total, five patients experienced a re-rupture. None of them were enrolled in the intervention group. Four were assigned to the non-operative group and one to the operative group. Three of the four patients assigned to the non-operative group should have been treated operative if treatment selection had been made using CARTA.

DISCUSSION

This thesis aimed to evaluate the reliability and validity of outcome measures used to evaluate tendon elongation and to investigate the effect of an individualized treatment algorithm on the patients' gait dynamics and tendon elongation within the first year after an Achilles tendon rupture.

Through the three studies of this thesis, we have investigated: 1) the reliability of outcome measurements for tendon elongation (CALM, ATRA, and ATLM), 2) the construct validity of indirect measures for tendon elongation (ATRA and ATLM) with a direct measure (CALM), 3) if gait dynamics, Achilles tendon elongation, and ATRS differ between patients using CARTA and patients treated as usual.

Evaluation of outcome measures for tendon elongation the first year after an Achilles tendon rupture

Reliability of measurements for tendon elongation

Brouwer et al. (56) compared the reliability between the CALM and EFOV method in 2018 and concluded that CALM resulted in a better agreement and higher reliability than EFOV in healthy individuals. EFOV has not been tested for reliability in patients. Brouwer et al. (56) also raise the question of a potential measurement error of using the un-injured leg as a reference when calculating tendon elongation. On the contrary, other studies did not find a statistically significant difference between legs (2,55). Though, a quite large variation between the two legs of individuals have been found, which is an additional error introduced in all measurements using the un-injured side as reference (55). Still, the non-injured leg is probably acceptable as a reference but is likely contributing to the measurement error seen when using CALM (75).

Similar to CALM, the reliability of ATRA and ATLM were significantly different when tested for elongation (difference between injured and non-injured side) (75) than for tendon length (injured/non-injured leg separately) (51). When tested for the legs separately, there was a slight advantage for ATLM (51). When tested for elongation, not only did the SEM- and MDC% increase drastically, but there was a clear advantage for ATRA, which showed a SEM% at 14.4% (ATLM 27.6%) and an MDC% at 40% (ATLM 75.9%).

The use of ATRA and CALM

ATRA and ATLM both show acceptable construct validity using CALM as gold standard. The width of the confidence intervals from the correlation estimates indicate that the correlations for ATRA and ATLM in relation to CALM are similar. The confidence intervals for both models are considered clinical acceptable. The validity of ATLM has not been tested before. The results for ATRA are in line with the correlation that Zellers et al. found (88). They showed a moderate relationship between ATRA and tendon elongation measured with the EFOV US.

Considering the results for both reliability and validity the ATRA can be recommended over ATLM due to the better reliability. The next question might be choosing between ATRA and CALM. You should probably choose a combination and differently according to who, where, and when to use them. ATRA is an indirect measure of tendon elongation whilst CALM is a direct measure. Moreover, to conduct ATRA, the only equipment required is a goniometer. To conduct CALM, an US machine is needed as well as more training in how to perform the measurement than for ATRA. Concerning validity, data is missing on how both ATRA and CALM is correlated to MRI. The validity study where CALM was evaluated against MRI did not show significant advantages (55) why CALM can be chosen as the gold standard.

When comparing the reliability data between ATRA and CALM, there are differences in absolute reliability between scores. Two months after injury, ATRA has a clear advantage with a SEM% at 14% and MDC% at 40%. Corresponding data for CALM is 26% and 74%. However, the reliability of CALM is seen to improve from 4 months until 12 months after injury, but not having 12 months data for ATRA limits this comparison. ATRA is possible for all clinicians to use. On the other hand, CALM demands access to an US scanner and training. Therefore, ATRA can be used as a screening tool of tendon elongation and a tool for communication between healthcare personnel. If need of further examination, CALM could be used to directly measure tendon elongation. Still, we do not know what is considered as the clinically relevant difference. At what degree of tendon elongation, the clinician should react is up to the single person and according to the symptoms experienced by the patient.

Tendon elongation the first year after an Achilles tendon rupture

Different lengths of the different parts of the Achilles tendon

In this thesis, the length between gastrocnemius and calcaneus has been measured. CALM can also measure the free length of the Achilles tendon, the distance from the distal tip of the soleus to the calcaneus (77). It has been suggested that the fiber bundles from gastrocnemius/soleus can move independently of each other, making it possible for the different displacement of the separate parts of the tendon during contraction (89). This result could imply that the three muscle bellies of triceps surae retract differently after rupture due to different elongation of the three parts of the tendon, which could result in altered walking and running due to alterations in force transmission (77). A study that examined patients two years after rupture showed the patients having a markedly elongated tendon, both the part deriving from gastrocnemius as well as soleus (90). When the studies in this thesis were initiated, the reliability of the free length of the tendon was not published (77). Also, the clinical experience using this measure indicates difficulties in localizing the distal tip of soleus on a patient within the first 6-12 months after injury. Data on reliability on patients are recommended before using CALM-the free length of the Achilles tendon.

The different lengths of the gastrocnemius and soleus part of the Achilles tendon have also affected the use of ATRA, where it has been proposed to measure ATRA both with knees flexed and extended (88,90). A previous validity study of ATRA showed a moderate correlation to elongation within the first year after rupture, both with the knee extended and flexed (88). However, they also showed that ATRA with the knee flexed at one year was related to mechanical tendon properties and heel-rise test performance. They, therefore, proposed ATRA with the knee flexed to be a better indicator of tendon elongation than with knee extended.

Development of tendon elongation over time

Among the patients in Study 2 (treated non-operative) (76), the tendon elongation decreased from two months (20.4 mm) to 12 months (15.6 mm) when measured with CALM. This result indicates that the tendon elongation decreased 4.8 mm from 2 to 12 months, above the SEM for CALM at 12 months (0.3 cm) (75).

Among the patients in the intervention group in Study 3 (67% of the patients were assigned to operative treatment), the tendon elongation increased from time for injury (16.4 mm) to 12

months (19.4 mm). This result indicates tendon elongation to increase 3 mm during the first 12 months after injury. However, this increase is at the same level as the SEM at 12 months (75).

The tendon elongation at 12 months among these two populations differs – the patients in Study 2 had 3.8 mm less tendon elongation than the patients in the intervention group in Study 3, which is above the SEM at 12 months (75). These two populations cannot be directly compared due to different sample sizes (Study 2 n= 84, Study 3 intervention group n=21) and the treatments received. Nonetheless, there might be a tendency for different development in tendon elongation over time for patients treated operative and non-operative.

Development among patients treated operative or non-operative

Interestingly, the tendencies of different patterns for tendon elongation can be recognized in the literature among patients receiving operative or non-operative treatment: studies where the patients are treated operative, the tendon elongation is increased until 3-6 months post-operative (45,48,49,63,91). That is both if measured radiographically (45,49,63), using US (91) or ATRA (48). On the contrary, in studies where patients were treated non-operative, the tendon elongation seemed to decrease the first year after rupture (75,76).

However, the differences in measuring and calculating elongation/separation of the tendon ends make a direct comparison between the above-mentioned studies difficult. In studies using ATRA (48) and US (91), it seems like the persistent tendon elongation at 12 months are alike, even though it increases or decreases over time; Aufwerber et al. (91) presented a tendon elongation of 1.65 cm after 12 months among patients treated operative (measured with EFOV), the patients in Study 2 (76) had an elongation at 1.56 cm after 12 months among patients treated non-operative (measured with CALM) (75). Both the tendon elongation presented by Aufwerber (91) and the results in Study 2 (76)are above SEM for CALM at 12 months (0.3 cm) (75) and therefore indicates an actual tendon elongation, above the measurement error. Carmont et al. (48) showed a tendon elongation around 6 degrees 12 months after injury (measured with ATRA, patients treated operative), the patients in Study 2 (treated non-operative) had an ATRA at 8.1 degrees (76). The SEM value for ATRA at 12 months are unknown, but the values above are over the SEM for ATRA at 2 months (2.3 degrees) (75) indicating both studies presenting a real tendon elongation above the measurement error.

The reason for tendon elongation

Why most patients with an Achilles tendon rupture come to struggle with an elongated tendon is not settled. Technical causes, including failure of the suture material of slipping the knot, could be possible among patients treated operative (45). In patients treated non-operative, it could result from a large gap at the rupture site when the treatment was initiated with subsequent healing in a lengthened position (92). Furthermore, since tendon elongation seems similar among all patients, other factors are most likely influencing. In recent years, different rehabilitation protocols and regimes have been proposed and evaluated, for example, considering early/late weight-bearing (63), early functional mobilization (91), and early controlled motion of the ankle (21). All without any clear effect on tendon elongation.

Individual treatment selection with the use of CARTA

No advantages for the intervention group

No statistical differences were indicated between the intervention and control groups, respectively, considering gait dynamics, tendon elongation, or PROM. No re-ruptures were seen in the intervention group, in comparison with four in the non-operative control group, and one in the operative control group. Of the four patients with re-rupture in the non-operative group, three would have been treated operatively if treatment selection had been made using CARTA. If CARTA might have the possibility to limit the risk of re-rupture among patients remains unclear, these speculations need to be evaluated further.

Deficits in gait dynamics at 12 months

Data for the intervention group showed statistically significant deficits in gait dynamics within the injured leg compared to the non-injured side, where the peak ankle plantarflexor moment was restored at 12 months. However, the peak ankle plantarflexor power during push-off was still reduced with a deficit of 7%. This result implies that the altered tendon properties observed may influence the translation of joint moment into effective propulsion, as represented by the peak power during push-off. However, the relevance of these findings is questionable since the knowledge of the clinically relevant deficit is missing. Agres et al. (93) presented restored plantarflexor moment 2-6 years after injury, as seen in Study 3. Speedtsberg et al. (40) reported restored peak positive plantarflexor power 4.5 years after injury. This result implies that the plantarflexor power deficit seen among the patients in study 3 might be restored over time.

Additionally, ATRS at 12 months showed high scores, meaning few problems, for activities involving walking (Items 6 and 7), and lower scores when asking about the patients' ability to run and jump (Items 8 and 9). This result could imply that activities requiring higher joint angular velocity and force development (for example, running and jumping) would better reveal relevant functional deficits one year after injury.

Furthermore, several studies report increased dorsiflexion in the injured ankle around 1-2 degrees (40,41,87,93), comparable to the intervention group in Study 3 (2.2 degrees), where some have seen a correlation to tendon elongation (87,93), and some has not (40). Nonetheless, the implications of an increased dorsiflexion of 1-2 degrees is questionable, both due to the clinical implication and the measurement's precision. Notably, the SEM has been presented by Meldrum et al. (94) to be 2.94 degrees.

Questioning the use of CARTA

CARTA was not superior to any of the two control groups in any of the investigated outcomes which raise the question if treatment selection using CARTA works. However, Study 3 had an exploratory design without a sample size calculation. Also, gait dynamics might not have been the optimal primary outcome measure as deficits are more likely seen in more demanding tasks like running and jumping. Regarding the two US examinations included in CARTA, the first, tendon overlap, is a quite simple decision to make and is reasonable from a clinical point of view since a minimum of overlapping tendon fibers must influence the possibility of a strong tendon healing (32). Still, the tendon overlap scan has not been validated. The second part, the measure of tendon elongation with CALM, has been evaluated as one of the objectives of this thesis. The measurement error for CALM within the first four days after injury was quite large (29% on a group level and 81% on an individual level). However, CALM at baseline was correlated to tendon elongation at 1-year follow-up (manuscript in press), indicating CALM to have a predictive value for outcome at one year.

CARTA is continuously being studied (20), and the results from the ongoing multicenter study will hopefully determine if treatment selection with CARTA is better than treatment as usual.

CONCLUSION

The results of the studies in this PhD thesis provide evidence of the following:

Copenhagen Achilles Length Measure (CALM) had excellent reliability but a rather large measurement error

CALM showed excellent relative reliability. The absolute reliability appeared to have quite a large measurement error. Still, CALM is recommended for use in research and clinical practice, but the results are recommended to be interpreted together with the measurement error.

ATRA is recommended as an indirect measure for tendon elongation

Both ATRA and ATLM showed acceptable construct validity for assessing tendon elongation after an Achilles tendon rupture. Since both relative and absolute reliability for elongation was better for ATRA than for ATLM, ATRA is recommended to use as an indirect outcome measure for tendon elongation.

Copenhagen Achilles Rupture Treatment Algorithm (CARTA) does not seem better than treatment as usual regarding gait dynamics

Individualized treatment using CARTA did not seem to have an advantage regarding gait dynamics, tendon elongation, or patient-reported outcome measures compared to patients treated as usual. Our results suggest statistically significant deficits in ankle plantarflexor power during walking together with a significant tendon elongation. However, given that this study is exploratory, this hypothesis must be tested with a confirmatory design.

PERSPECTIVES AND FURTHER RESEARCH

This thesis provides valuable knowledge about outcome measures for tendon elongation together with preliminary data from patients treated according to an individualized treatment algorithm in a randomized set-up. Still, it raises further questions which hopefully can be answered in future research.

The studies regarding how to measure elongation in this thesis provide detailed descriptions of how tendon elongation can be measured indirectly and directly. ATRA is recommended for individual evaluation in clinical practice and CALM for those with access to a US machine. Both can be used in the field of research. Most of all, it is crucial that outcome measures are used the same way, so that results can be interpreted and compared on a group level. Future research should focus on investigating what a clinically relevant tendon elongation is to better know when the patients are affected by an elongated tendon and when they are not.

CARTA did not seem to better gait dynamics. CARTA is being studied continuously, and upcoming studies will hopefully answer whether treatment selection using CARTA could positively limit the incidence of re-ruptures and present an optimized functional outcome. Future research on CARTA should also focus on activities requiring a higher level of joint angular velocity and force development, like running and jumping, which may better reveal functional deficits than gait dynamics.

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APPENDIX

PAPER 1

PAPER 2

PAPER 3

1

Reliability of the Copenhagen Achilles Length Measure (CALM) on patients with an Achilles tendon rupture

Hansen MS, Kristensen MT, Budolfsen T, Ellegaard K, Hölmich P, Barfod KW.

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Reliability of the Copenhagen Achilles length measure (CALM) on patients with an Achilles tendon rupture

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Abstract

Purpose The primary objective was to examine the reliability of the Copenhagen Achilles length measure (CALM) in patients with an Achilles tendon rupture and secondary to examine the reliability of Achilles tendon resting angle (ATRA) and Achilles tendon length measure (ATLM).

Method The study was executed as a cross-sectional study on two different groups: one focused on CALM and the other on ATRA/ATLM. CALM was performed on 56 patients at four timepoints during the first year after injury, whereas ATRA/ATLM were carried out on 28 patients. Intra- and inter-rater reliabilities were determined using the intra-class correlation coefficient (ICC), the standard error of the measurement (SEM), and the minimal detectable change (MDC).

Results For CALM, all measurements, both for injured and non-injured sides as well as for elongation, indicated excellent relative reliability (ICC ≥ 0.75). During the four timepoints, the inter-rater absolute reliability had an SEM that ranged between 0.3 and 0.8 cm (1–4 SEM%) for injured and non-injured sides and 0.3–0.6 cm (18–29 SEM%) for elongation. On an individual level, the inter-rater absolute reliability had an MDC ranging between 0.8 and 2.2 cm (4–11 MDC%) for injured and non-injured sides and 0.8–1.7 cm (47–81 MDC%) for elongation. In the case of ATRA, relative reliability was excellent (ICC ≥ 0.75), and for ATLM, it was fair to excellent (ICC 0.58–0.79). ATRA presented a lower measurement error than ATLM.

Conclusion Copenhagen Achilles length measure showed excellent relative reliability, but had a significant measurement error at four timepoints the first year following an Achilles tendon rupture.

Level of evidence II.

Keywords Achilles tendon rupture · Elongation · Ultrasonographic measure · Reliability

Abbreviations

CALM	Copenhagen Achilles length measure
ATRA	Achilles tendon resting angle
ATLM	Achilles tendon length measure
ICC	Intraclass correlation coefficient
SEM	Standard error measurement
MDC	Minimal detectable change
ATR	Achilles tendon rupture
US	Ultrasonographic
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
CI	Confidence interval
SD	Standard deviation

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Introduction

Acute Achilles tendon rupture (ATR) is devastating in that it affects the physical and psychological health of the patient [16, 21], who may never return to the same level of physical activity as pre-injury [14, 21, 28]. The consequences resulting from an ATR and the increasing number of patients experiencing ATR [12] suggest that there is a need for improved treatment and rehabilitation.

A common and often overlooked complication after an ATR is tendon elongation, which has been proposed as a factor-limiting calf muscle volume and plantar flexion strength [16]. Clinical outcome is positively correlated with less elongation [17]. Valid and reliable measurements of tendon elongation after ATR are needed, both clinically and for research.

The literature presents several methods on how to measure elongation after an ATR. The Achilles tendon resting angle (ATRA) [7] and Achilles tendon length measure (ATLM) [13] are both indirect measurements that use the resting angle of the ankle joint as a surrogate measure for tendon elongation. In addition, different ultrasonographic (US) measurements have been used [2],either by combining the use of US imaging and motion analysis system [25] or simply with US [3, 24]. The US measurements have been conducted in several ways, e.g., by applying extended field-of-view panorama images [24] or by freehand measurement of distance between landmarks [3]. Furthermore, radiostereometric analysis with radio-opaque markers placed into the tendon ends [23] and MRI [16] has been used to measure elongation after an ATR.

The Copenhagen Achilles length measure (CALM) [3] is a US-based measurement that localises the proximal and distal landmarks of the Achilles tendon. The proximal landmark is defined at the distal tip of the medial gastrocnemius muscle tendon junction and the distal landmark at tendon insertion at calcaneus. The distance between landmarks is measured with a tape measure. CALM has showed good validity and reliability when investigating healthy individuals [3, 6], but no tests of reliability on patients have been published [6, 24]. When looking at the tendon elongation (difference between the injured and non-injured sides), you add the measurement error of both measurements to the calculation of the reliability. Therefore, an investigation of reliability of the difference is needed and the reliability values on healthy individuals cannot be used when evaluating elongation on patients.

ATRA [7] and ATLM [13] both originate from Matles' test [20]. They are based on the same concept, but differ in terms of the way in which they measure the position of the foot; ATRA measures the angle in the ankle joint with a goniometer, whereas ATLM measures the distance from the foot down to the underlay with a ruler. The reliability of ATRA and ATLM when measuring tendon length on both the injured and the non-injured sides has been investigated in patients in a previous article [13]. Unfortunately, the study did not investigate the reliability for elongation (the difference between the injured and non-injured side), which is the clinical relevant measure most often used in clinical practise.

The primary purpose of this study was to examine the relative and absolute reliability of CALM at the time of rupture and at 2, 4, and 12 month post-rupture in patients with an ATR. Our hypothesis was that CALM had inter- and intra-rater reliabilities above 0.7 in ICC at all timepoints, and the measurements were able to detect differences above 1.5 cm (MDC < 1.5 cm). The secondary purpose was to look at the relative and absolute reliability of measurements of tendon elongation measured with ATRA and ATLM.

Materials and methods

This study was performed as a cross-sectional study following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [26] guideline. Patients were recruited from the Copenhagen University Hospital Hvidovre.

Patients

For the examination of the reliability of CALM, 56 patients (group A) were recruited between April 2016 and May 2017. For the examination of the reliability, ATRA's and ATLM's capabilities to measure elongation from 28 patients (group B) were investigated. All 28 patients participated in a previous study [13] between April 2014 and July 2015, where only reliability for injured and non-injured side separately (tendon length) was reported and not tendon elongation (the difference between injured and non-injured sides). Both groups were selected through consecutive sampling.

Inclusion criteria for both populations were: minimum 18 years of age; diagnosed of ATR within the last 5 days; able to speak; and understand Danish. Exclusion criteria were: previous ATR or operation on the Achilles tendon; rupture within 1 cm from calcaneus; treatment with fluoroquinolone or cortisone within the last 6 months; arterial insufficiency in the legs; terminal disease; or a critical medical illness.

The patients received oral and written information before written consent was obtained. Permission to handle data from the Danish Data Protection Agency was acquired (HVH-2014-002, I-Suite no. 02608 for CALM and journal number 2013-41-2024 for ATRA/ATLM). This study was reported to the Capital Region's Research Ethics Committee,

which deemed that no approval was required (journal number: H-4-2013-176 for CALM and H-4-2013-FSP for ATRA/ATLM).

Treatment/rehabilitation programme

Patients were treated either operatively or non-operatively. All patients followed the same rehabilitation protocol: cast in maximal equinus position for the first 2 weeks and a DJO Aircast Walker with three wedges from weeks 3–8 positioning the ankle joint in 20°–30° equinus. The ankle was gradually brought to a neutral position by removing one wedge every second week. Full weight-bearing on the injured limb was allowed from week 3. From weeks 8 to 16, the patients followed a standardised physiotherapy-led exercise program twice weekly [1].

The Copenhagen Achilles length measure (CALM)

CALM was measured as described by Barfod et al. [3]. The length of the Achilles tendon was defined as the distance between the tendon insertion at the calcaneus and the distal tip of the medial gastrocnemius muscle tendon junction (Fig. 1) as previously described by Rees et al. [22]. The patient was positioned prone with the knee flexed 10°. A foam pad was placed anterior to (below) the ankle joint with the feet resting in a relaxed manner against it. Using a goniometer, the ankle joint was positioned in 10° of plantar flexion by adjusting the foam pad (Fig. 2).

First, landmarks were identified and marked. The distal landmark was the posterior and most superior parts of the calcaneus in the midline, which on sagittal US examination was identified as the point, where the cortical bone and its underlying shadow ended. The proximal landmark was the distal tip of the medial gastrocnemius head, in which on sagittal US examination was recognised as the point, where the most distal muscular fibres were inserted into deep crural fascia. After identifying the landmark, it was placed in the middle of the image with the probe oriented in the sagittal plane. A 21 gauge needle was then introduced between the probe and the surface of the skin, projecting the landmark to the skin. Finally, this point was marked on the skin with a removable marker. The direct distance between landmarks was measured with a tape measure (accuracy 0.1 cm, the same tape measure for all measurements) following the curves of the leg.

Ultrasound assessments were performed using a Hitachi Aloka Noblus ultrasound system that was applied in the daily clinical praxis and was well known to both raters. The same pre-set was implemented for all cases: high definition dynamic tissue harmonic imaging with Hd-THI-R level.

Achilles tendon resting angle (ATRA) and Achilles tendon length measure (ATLM)

ATRA and ATLM were measured as described by Hansen et al. [13]. The patient was positioned prone with his/her knees flexed 90°. Points of reference were palpated and marked with a pen. For ATRA, the points of reference constituted the centre of the fifth metatarsal head and the distal tip of the lateral malleolus and caput fibula. For ATLM, it was the centre of the fifth metatarsal head. A standard 30 cm-long goniometer with 1° increments was used for ATRA. The centre of the goniometer was put over the malleolus and the two arms of the goniometer against the other points of reference. In the case of ATLM, a long ruler was placed perpendicular to the underlay. ATLM was measured as the distance in centimetres between the head of the fifth metatarsal and the underlay.

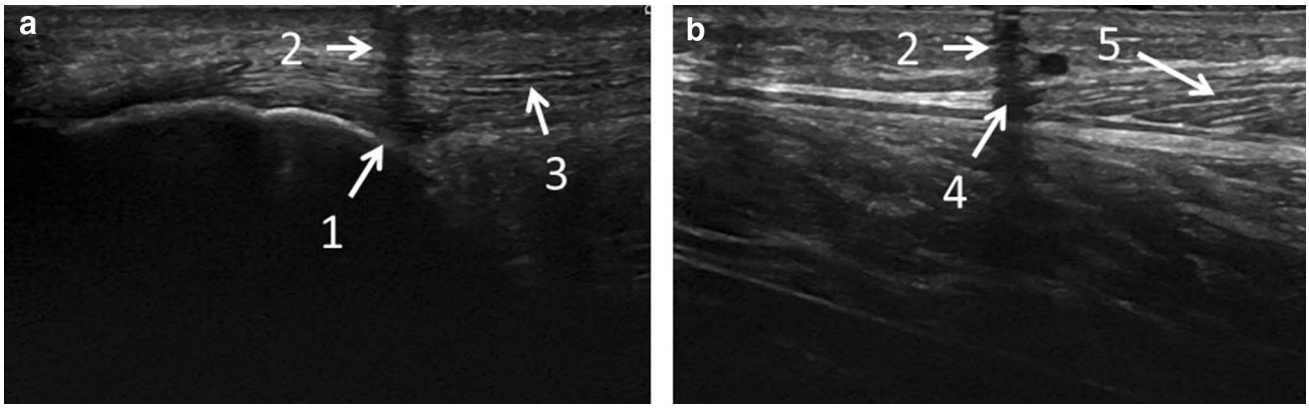

Fig. 1 Sagittal US pictures showing the landmarks. **a** (1) distal landmark—the posterior superior corner of calcaneus. (2) Shadow of a 21 gauge needle projecting the landmarks to the skin. (3) Achilles tendon. **b** (4) Proximal landmark—the most distal muscle fibres insertion into the deep fascia at the distal tip of the medial gastrocnemius head. (5) Gastrocnemius muscle

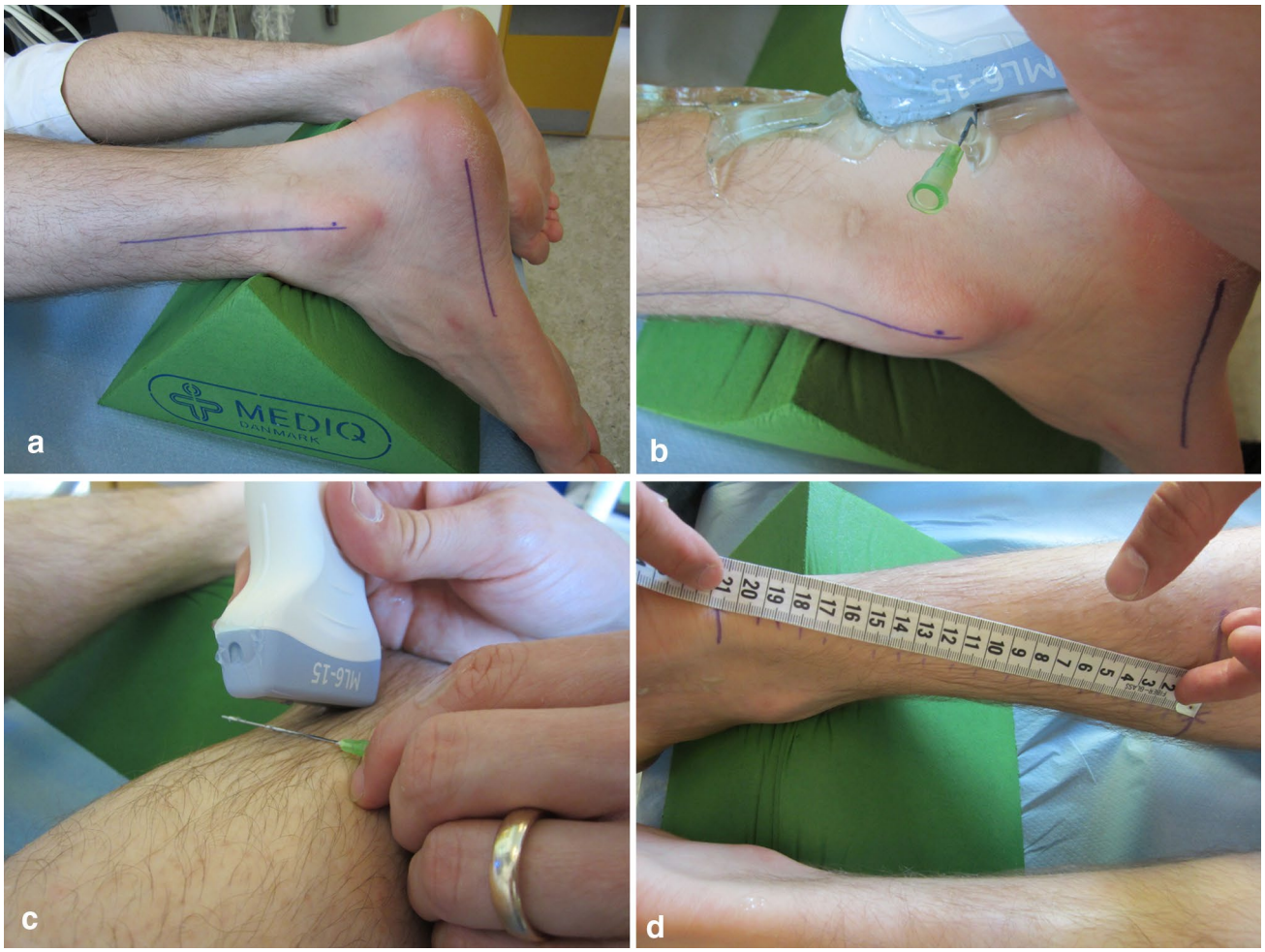

Fig. 2 Method of performing CALM: **a** position of the patient with 10° of plantar flexion in the ankle joint adjusted with the foam pad, (**b**+**c**) needle was introduced between the probe and the surface of the skin projecting the landmark to the skin. This landmark was marked on the skin with a removable marker, and (**d**) distance between landmarks was finally measured with a tape measure (accuracy 0.1 cm)

Setup for the intra- and inter-rater testings

CALM was measured at the time of rupture (0–4 days after injury) (T1) and at 2 (T2), 4 (T3), and 12 (T4) month post-rupture, respectively. The setup was cross section, meaning that the same patients were not followed over time. Rater A started all test sessions, followed by rater B, and finally, rater A finished the session. The raters were blinded to each other and their own measurements. The raters were alone in the examination room while conducting the measurements. To ensure that the first rater did not affect the second rater's measurements by seeing the marks drawn on the leg, the marks were removed with alcohol. To blind the raters to their own results, a blank strip of paper was used to measure the distance between the landmarks. After all the measurements were carried out, the paper strips were measured with a tape measure (precision 1 mm).

The reliability of the measuring of elongation with ATRA and ATLM was investigated at 8 and 16 weeks after injury with data from a previous study [13]. At 8 weeks, both intra- and inter-rater testings were performed, and at 16 weeks, only intra-rater testing was implemented as previously described [13]. The testers were blinded to each other as well as their own ratings [13].

Statistical analysis

The sample size for group A was decided based on the sample size of a previous study that examined both legs from 19 healthy subjects [3] and logistical considerations. The aim was to include 20 patients at each stage of the study (T1–T4, respectively), 80 patients in total.

Paired *t* test was used to investigate differences between the raters. Intraclass correlation coefficient (ICC

2.1) with 95% confidence interval (a two-way random-effects model, absolute agreement, and single measure) was applied to investigate the inter- and intra-rater reliabilities [27]. According to Fleiss' classification, an ICC above 0.75 indicates excellent reliability, between 0.40 and 0.75 as fair to good reliability and below 0.40 as poor reliability [11].

To assess absolute reliability, standard error of measurement (SEM) and minimal detectable change (MDC) were calculated. SEM can be used to indicate that the smallest change needed to indicate a real change at a group level, while MDC indicates a real change required for one single person [10]. SEM was calculated as $SD \times \sqrt{(1 - ICC)}$, whereas SD is the standard deviation of the cumulative means of raters A and B's measurements from all subjects, respectively [15, 27]. MDC was calculated at 95% confidence level as $1.96 \times SEM \times \sqrt{2}$ [4]. To be able to compare the measurement error of the two tests with different scales, SEM and MDC were expressed as the SEM% = (SEM/mean) × 100 and the MDC% = (MDC/mean) × 100, where mean was the cumulative mean tendon length of assessors A and B's measurements [18].

Bland–Altman plots were used for qualitative assessment to illustrate the degree of agreement between raters A and B's measurements [5]. It is recommended that 95% of the data should fall within the mean ± 2SDs of the differences for raters A and B's measurements, which corresponds to the 95% CI.

All analyses were executed using SPSS version 19.0 (SPSS Inc, 233 S Wacker Dr, 11th Floor, 156 Chicago, IL 60606). The level of significance was set at p less than 0.05, and all statistical tests were two-tailed.

Results

Group A consisted of 56 patients with a mean age of 43 years (SD 10.7, [range 23–76]), made up of 12 women and 44 men. Four patients were treated operatively and 52 patients were treated non-operatively. Group B consisted of 28 patients with a mean age of 42 years (SD 9.7, [range 28–70]), consisting of 5 women and 23 men. All 28 patients were treated non-operatively [13]. Descriptive statistics for both groups can be found in Table 1.

Tendon length and elongation

Tendon length measured with CALM in group A showed the length of the injured tendon to be 20.4 cm at the time of rupture and 19.9 cm after 1 year. The length of the non-injured tendon was 17.9–18.6 cm during the first year after injury. Tendon elongation was calculated as the injured side minus the non-injured side and was 2.1 cm at the time of rupture and 1.6 cm at 12 months (Table 2).

The indirect measurement for elongation using ATRA and ATLM in group B was calculated as the injured side minus the non-injured side for ATRA and vice versa for ATLM (Tables 4, 5). At week 8, ATRA was 15.8° and 12.1° at week 16. Elongation measured with ATLM was 2.8 cm and 1.8 cm at the same timepoints. Results for injured and non-injured sides for ATLM/ATLM have been published previous to this study [13].

Relative reliability of CALM

All measurements, both for the injured and the non-injured sides, as well as for elongation, indicated excellent relative reliability (ICC ≥ 0.75), both considering intra-rater and inter-rater reliabilities, as presented in Tables 2 and 3. The

Table 1 Descriptive statistic for group A (divided at the four timepoints) and group B

Variable	Levels	Group A 0–4 days	Group A 2 months	Group A 4 months	Group A 12 months	Group B
N		14	13	14	15	28
Sex	W	2 (14.3)	4 (30.8)	2 (14.3)	4 (26.7)	5 (17.8)
	M	12 (85.7)	9 (69.2)	12 (85.7)	11 (73.3)	23 (82.2)
Age (year)		40.2 (5.5)	40.9 (12.4)	46.9 (12.4)	44.7 (10.7)	42 (9.7)
Weight (k)		87.7 (21.3)	88.3 (11.8)	85.6 (13.2)	81.8 (19.1)	88.4 (15.9)
	Missing	3	1	1	1	
Height (cm)		179.4 (8.7)	180.0 (6.1)	177.3 (6.1)	177.3 (8.6)	174.2 (32.7)
	Missing	5	1			
Treatment	NON	12	11	14	15	28
	OPR	2	2	0	0	0

Data are presented as count (%) for dichotomous data and mean (SD) for continuous data

W women, *M* men, *NON* non-operative treatment, *OPR* operative treatment

Table 2 Intra-rater reliability CALM (injured and non-injured sides and for elongation)

	Rater A_{t1}	Rater A_{t2}	Difference (95% CI)	*p* values	ICC (95% CI)	SEM (SEM%)	MDC (MDC%)
Injured side							
Day 0, *n* = 14	**20.4 (1.9)**	20.6 (1.9)	−0.2 (−0.42; 0.17)	n.s	0.97 (0.90; 0.99)	0.3 (1.5%)	0.8 (3.9%)
2 months, *n* = 13	20.1 (2.3)	20.1 (2.3)	0.0 (−0.22; −0.22)	n.s	0.99 (0.96; 0.99)	0.2 (0.9%)	0.6 (2.9%)
4 months, *n* = 14	20.5 (1.6)	20.6 (1.9)	−0.1 (−0.35; 0.14)	n.s	0.97 (0.92; 0.99)	0.3 (1.4%)	0.8 (3.9%)
12 months, *n* = 15	**19.9 (1.8)**	19.9 (1.9)	−0.0 (−0.33; 0.17)	n.s	0.97 (0.92; 0.99)	0.3 (1.5%)	0.8 (4.0%)
Non-injured side							
Day 0, *n* = 14	18.3 (2.4)	18.5 (2.3)	−0.2 (−0.48; 0.07)	n.s	0.98 (0.93; 0.99)	0.3 (1.6%)	0.8 (4.3%)
2 months, *n* = 13	17.9 (2.1)	17.8 (1.9)	0.1 (−0.14; 0.31)	n.s	0.98 (0.95; 0.99)	0.3 (1.7%)	0.8 (4.5%)
4 months, *n* = 14	**18.6 (1.8)**	**18.8 (1.9)**	−0.2 (−0.44; −0.07)	0.01	0.98 (0.88; 0.99)	0.2 (1.1%)	0.6 (3.2%)
12 months, *n* = 15	18.2 (2.1)	18.2 (2.1)	0.0 (−0.25; 0.24)	n.s	0.98 (0.94; 0.99)	0.3 (1.6%)	0.8 (4.4%)
Elongation							
Day 0, *n* = 14	2.1 (1.4)	2.0 (1.4)	0.1 (−0.26; 0.43)	n.s	0.92 (0.76; 0.97)	0.4 (19%)	1.1 (52.4%)
2 months, *n* = 13	2.2 (1.3)	2.3 (1.4)	−0.1 (−0.40; 0.25)	n.s	0.92 (0.77; 0.98)	0.4 (17.4%)	1.1 (47.8%)
4 months, *n* = 14	1.9 (1.2)	1.8 (1.3)	0.1 (−0.08; 0.38)	n.s	0.94 (0.83; 0.98)	0.3 (16.7%)	0.8 (44.4%)
12 months, *n* = 15	1.6 (0.9)	1.7 (1.1)	−0.1 (−0.38; 0.24)	n.s	0.85 (0.62; 0.95)	0.3 (17.6%)	0.8 (47.1%)

Data are cm, mean (SD), otherwise as stated. Day 0 = 0–4 days after injury

Bolded text indicates a statistically significant difference between measures tested with paired *t* test

n.s non-significant, *ICC* intra-class correlation, *CI* 95% confidence interval, *SEM* standard error of measurement, *MDC* minimal detectable change, A_{t1} rater A first measure, A_{t2} rater A second measure

Table 3 Inter-rater reliability CALM (injured and non-injured sides and for elongation)

	Rater A	Rater B	Difference (95% CI)	*p* values	ICC (95% CI)	SEM (SEM%)	MDC (MDC%)
Injured side							
Day 0, *n* = 14	**20.4 (1.9)**	**21.1 (1.9)**	−0.7 (−1.30; −0.14)	0.02	0.84 (0.41; 0.95)	0.8 (3.9%)	2.2 (10.6%)
2 months, *n* = 13	20.1 (2.3)	20.0 (2.4)	0.1 (−0.4; −0.59)	n.s	0.95 (0.84; 0.98)	0.5 (2.5%)	1.4 (7.0%)
4 months, *n* = 14	20.5 (1.6)	20.3 (1.9)	0.2 (−0.15; 0.58)	n.s	0.93 (0.81; 0.97)	0.5 (2.5%)	1.4 (6.9%)
12 months, *n* = 15	**19.9 (1.8)**	**19.6 (1.7)**	0.3 (0.02; 0.50)	0.04	0.96 (0.86; 0.99)	0.3 (1.5%)	0.8 (4.1%)
Non-injured side							
Day 0, *n* = 14	18.3 (2.4)	18.5 (2.5)	−0.2 (−0.77; 0.23)	n.s	0.94 (0.83; 0.98)	0.6 (3.3%)	1.7 (9.3%)
2 months, *n* = 13	17.9 (2.1)	17.9 (2.1)	0.0 (−0.42; 0.39)	n.s	0.95 (0.85; 0.99)	0.5 (2.8%)	1.4 (7.8%)
4 months, *n* = 14	**18.6 (1.8)**	18.5 (2.0)	0.1 (−0.35; −0.44)	n.s	0.94 (0.82; 0.98)	0.5 (2.7%)	1.4 (7.5%)
12 months, *n* = 15	18.2 (2.1)	18.0 (2.1)	0.2 (−0.01; −0.49)	n.s	0.97 (0.91; 0.99)	0.4 (2.2%)	1.1 (6.1%)
Elongation							
Day 0, *n* = 14	2.1 (1.4)	2.6 (1.2)	−0.5 (−0.95; 0.05)	n.s	0.79 (0.42; 0.93)	0.6 (28.6%)	1.7 (80.9%)
2 months, *n* = 13	2.2 (1.3)	2.1 (1.3)	0.1 (−0.43;0. 69)	n.s	0.75 (0.37; 0.92)	0.6 (26.1%)	1.7 (73.9%)
4 months, *n* = 14	1.9 (1.2)	1.7 (1.3)	0.2 (−0.12; 0.46)	n.s	0.90 (0.75; 0.97)	0.4 (22.2%)	1.1 (61.1%)
12 months, *n* = 15	1.6 (0.9)	1.6 (1.0)	0.0 (−0.26; 0.30)	n.s	0.87 (0.65; 0.95)	0.3 (17.6%)	0.8 (47.0%)

Data are centimeters, mean (SD), otherwise as stated. Day 0 = 0–4 days after injury

Bolded text indicates a statistically significant difference between raters tested with paired *t* test

n.s non-significant, *ICC* intra-class correlation, *CI* 95% confidence interval, *SEM* standard error of measurement, *MDC* minimal detectable change

mean differences between measurements were all within 0.2 mm, except for two cases, where the differences were 0.3 mm and 0.7 mm (Tables 2, 3).

Absolute reliability of CALM

Measurement error detected on a group level for intra-rater ranged between 0.2 and 0.3 cm (1–2 SEM%) for injured and non-injured sides and 0.3–0.4 cm (17–19 SEM%) for

elongation (Table 2). Corresponding results for inter-rater reliability were 0.3–0.8 cm (1–4 SEM%) and 0.3–0.6 cm (18–29 SEM%) (Table 3).

On an individual level, the intra-rater absolute reliability was 0.6–0.8 cm (3–4 MDC%) for injured and non-injured sides and 0.8–1.1 cm (44–52 MDC%) for elongation (Table 2). Corresponding results for inter-rater reliability were 0.8–2.2 cm (4–11 MDC%) and 0.8–1.7 cm (47–81 MDC%) (Table 3).

Only a few outliers were observed (above the 95% CI) as illustrated in the Bland–Altman plots (Fig. 3a–d).

Relative and absolute reliability of elongation measured with ATRA and ATLM

Relative reliability of elongation measured with ATRA was excellent (ICC ≥ 0.75) for both intra- and inter-rater and fair to excellent (0.58–0.79) when measured with ATLM. The measurement error on a group level for intra- and inter-rater during the timepoints ranged between 1.1–2.3° (7–14 SEM%) for ATRA and 0.4–0.8 cm (22–28 SEM%) for ATLM. On an individual level, the measurement error for intra- and inter-rater ranged between 3.1° and 6.4° (19–40 MDC%) for ATRA and 1.1–2.2 cm (61–76 MDC%) for ATLM (Tables 4, 5).

Discussion

The main finding of the present study was that CALM had excellent relative intra- and inter-rater reliabilities, both in terms of its ability to measure tendon length and elongation. Thus, it confirmed our hypothesis of ICC above 0.70. Absolute reliability was excellent for the measurement of tendon length on both injured and non-injured sides with a measurement error ranging from 0.9 to 10.6%

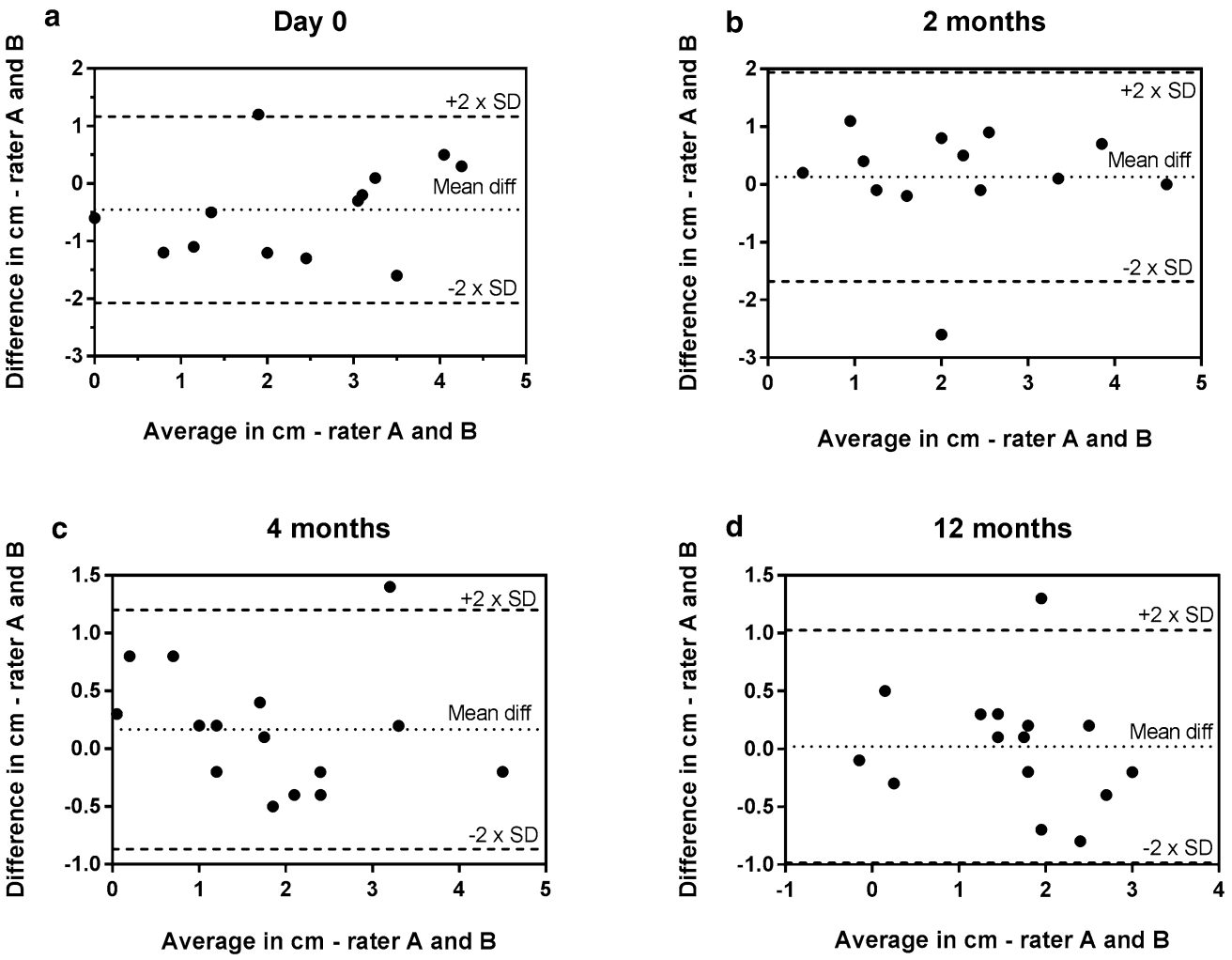

Fig. 3 Bland–Altman plot. The small dashed line indicates the average of the differences, while large dashed lines indicate the 95% confidence intervals corresponding to the mean ± 2SDs of the differences. Day 0 (**a**), 2 months (**b**), 4 months (**c**), 12 months (**d**)

Table 4 Intra-rater reliability ATRA and ATLM ($n = 28$)

	Rater A_{t1}	Rater A_{t2}	Rater A_{mean}	Difference (95% CI)	*p* values	ICC (95% CI)	SEM (SEM%)	MDC (MDC%)
ATRA 8 weeks	15.8° (5.6)	16.2° (5.5)	16.0° (5.6)	−0.4° (−1.01; 0.19)	n.s	0.96 (0.92; 0.98)	1.1° (6.9%)	3.1° (19.4%)
ATLM 8 weeks	2.8 cm (1.5)	2.6 cm (1.5)	2.7 cm (1.4)	0.2 cm (−0.31; 0.57)	n.s	0.71 (0.47; 0.86)	0.7 cm (25.9%)	1.9 cm (70.4%)
ATRA 16 weeks	12.1° (5.8)	12.3° (5.5)	12.2° (5.5)	−0.2° (1.07; 0.69)	n.s	0.93 (0.85; 0.97)	1.5° (12.3%)	4.2° (34.4%)
ATLM 16 weeks	1.8 cm (0.9)	1.8 cm (1.0)	1.8 cm (0.9)	0.0 cm (−0.32; 0.19)	n.s	0.79 (0.59; 0.90)	0.4 cm (22.2%)	1.1 cm (61.1%)

Data are mean (SD), otherwise as stated

n.s non-significant, *ICC* intra-class correlation, *CI* 95% confidence interval, *SEM* standard error of measurement, *MDC* minimal detectable change, A_{t1} rater A first measure, A_{t2} rater A second measure

Table 5 Inter-rater reliability ATRA and ATLM ($n = 28$)

	Rater A	Rater B	Rater A + B	Difference (95% CI)	*p* values	ICC (95% CI)	SEM (SEM%)	MDC (MDC%)
ATRA 8 weeks	15.8° (5.6)	16.2° (6.8)	16.0° (6.0)	−0.4° (−1.76; 0.91)	n.s	0.85 (0.70; 0.93)	2.3° (14.4%)	6.4° (40.0%)
ATLM 8 weeks	2.8 cm (1.5)	3.0 cm (1.2)	2.9 cm (1.2)	−0.2 cm (−0.68; 0.26)	n.s	0.58 (0.27; 0.78)	0.8 cm (27.6%)	2.2 cm (75.9%)

Data are mean (SD), otherwise as stated

n.s non-significant, *ICC* intra-class correlation, *CI* 95% confidence interval, *SEM* standard error of measurement, *MDC* minimal detectable change

on an individual level, indicating that the measurement is reliable for both research and clinical purposes. However, when investigating the absolute reliability of CALM for measurement of elongation, the measurement error rose to 18–29% on a group level and to 47–81% on an individual level. Our hypothesis of a measurement error below 1.5 cm (MDC < 1.5 cm) was rejected during the early timepoints (0 and 8 weeks), but confirmed at 4 and 12 months. Therefore, CALM should be used with precaution for the evaluation of elongation of the injured Achilles in the period up to 4 month postrupture.

The reliability of CALM seems to change over time, having an advantage at later timepoints. One reason could be the change of how the landmarks appear during the first year after injury. Hematoma might be blurring the landmarks in the acute phase, and the resulting hypotrophy of m. triceps surae [19] after 2 months of immobilisation may also affect the appearance of the distal tip of medial gastrocnemius by making the distal muscular fibres insertion to the fascia less visible. Another factor, which may affect the results in the acute phase, is problems with positioning the ankle joint correctly if the patient is in pain or if the ankle is tensed due to concerns regarding the acute injury.

What matters in relation to clinical investigation of patients and their recovery is the tendon elongation. To our knowledge, CALM is the only US measurement for which the reliability of the measurement of elongation has been investigated. Our study demonstrates that the reliability for the injured and the non-injured sides each has higher ICC levels and a lower measurement error than the reliability for elongation. Previous studies investigating the reliability of both CALM [3], other US measurements [6, 24] as well as ATRA and ATLM [8, 13] have measured the tendon length for the injured and uninjured legs separately and have not investigated the reliability of the elongation. CALM is fully comparable to other measurements when investigating the reliability of the measurement of tendon length [6, 8, 13, 24].

The absolute measurement error (SEM and MDC) of elongation is comparable to that of tendon length. SEM% and MDC% are inflated due to the mean of comparison. The percentual difference increases, as we are evaluating distances of approximately 2 cm instead of 20 cm. Therefore, similar results must be expected if the reliability of measurement of elongation performed with other US measurements should be investigated.

The main finding when investigating the reliability of measurements of elongation performed with ATRA and ATLM was that ATRA showed higher relative reliability and measurement error than ATLM. The reliability of measures of the injured and non-injured legs separately has been investigated previously [13]. ICC levels were higher and the measurement error lower than for elongation. In addition, the reliability for non-injured and injured sides, respectively, showed that ATLM had a slightly lower measurement error than ATRA, which also differs from the reliability of elongation, where ATRA has a smaller measurement error than

ATLM. Hereby, the present study suggests that ATRA is more reliable than ATLM when measuring elongation.

The mean Achilles tendon elongation found in this study (2.1 cm at the time of injury and 1.6 cm 1 year after the injury) of mainly non-operated patients is comparable to what other studies investigating tendon elongation have reported. Zellers et al. found 1.6 cm elongation 18 months after injury among patients treated operatively using extended field-of-view panorama images [29]. Though, using different US methods might limit a direct comparison. Silbernagel et al. present an elongation of 2.6 cm after one year [25] on a small cohort of eight patients treated operatively, also using extended field-of-view panorama images. Studies investigating lengthening after implantation of radiographic markers during operation present less elongation; Kangas et al. conclude an elongation of 0.5 cm 1 year after injury [17]. Their results are similar to a recent publication by Eliasson et al., who measured an elongation of 0.8 cm 1 year post-operation [9]. However, one should keep in mind that measurements with radiographic markers are not an expression of the actual elongation after rupture but only of the elongation of the tissue between the markers in the period after implantation of the markers. As the markers are implanted after the tendon has ruptured, they cannot illustrate the actual tendon elongation.

The limited number of patients at all timepoints serves as the largest limitation for the reliability assessments of CALM. The combination of the natural spread in results, outliers, and the measurement error (reflected in the relatively large CI) indicates that a larger sample size would be preferable. The cross-sectional design was a feasible way to perform the study, but did not allow to follow patients over time. Therefore, the results of change in tendon length and elongation over time should be interpreted with caution.

Differences between study groups might have influenced results due to the differences in age and sex between groups, and this might in turn influence the clarity of the landmarks. In addition, only four of the patients had operative treatment due to the present standard treatment. The operative treatment could affect the landmarks and make them more difficult to identify.

Blinding the raters' own results while conducting CALM by applying a tape measure without markings introduced an extra source of error when compared to the normal setting and may have contributed to the significant measurement error. Rater A was the first to conduct the measurement followed by rater B. Even though the results for CALM do not imply a case of learning effect of the measurement, a randomised order regarding who the measurement procedure started with would have been preferred (as done for the original study of ATRA and ATLM [13]).

The results of this study suggest that CALM can be recommended for the measurement of elongation on a group level. If used for the measurement of elongation on an individual level, the tests on the patients should preferably be carried out by the same tester, as it reduces the measurement error for elongation from 81 to 52%. If more testers are present, it is important that they take the time to train and calibrate the measurement before putting it to use in clinical work.

CALM has been found to be more reliable than extended field-of-view imaging [6] and can be proposed as the measurement of choice for investigation of elongation after an ATR.

Conclusion

CALM showed excellent relative reliability, but had quite a large measurement error at four timepoints during the first year following an ATR. CALM is recommended for use in research and in clinical practice, but the results need to be interpreted with caution due to the measurement error, especially the first 4 month postrupture. The reliability needs to be further investigated on a larger sample to establish the use on an individual level.

ATRA showed a higher level of reliability than ATLM for indirect measurement of tendon elongation, but further investigation considering the validity of these measurements is needed.

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Authors' contribution KWB and TB initiated the study, which was planned together with KE. KE was also responsible for training TB and the other rater in the US examination as well as calibrating their technique. MSH was responsible for the practical considerations of conducting the study in the usual clinical setting. MSH and MTK conducted the statistical analysis. MSH, MTK, KWB, and PH have analysed the results together. MSH made the first draft of the manuscript, which has been corrected after supervision from KWB. All authors have been involved in revising and drafting the manuscript.

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Compliance with ethical standards

Conflict of interest All authors declare that they have no conflict of interest.

Ethical approval This study was deemed that not approval was required (journal number: H-4-2013-176 for CALM and H-4-2013-FSP for ATRA/ATLM) by the Capital Region's Research Ethics Committee.

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2

The Achilles Tendon Length Measure and the Achilles Tendon Resting Angle show acceptable construct validity using the Copenhagen Achilles Length Measure as gold standard

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The Achilles Tendon Length Measure and the Achilles Tendon Resting Angle show acceptable construct validity using the Copenhagen Achilles Length Measure as gold standard

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ABSTRACT

Background: Elongation of the Achilles tendon after rupture is a frequent complication. The Achilles Tendon Length Measure (ATLM) and the Achilles Tendon Resting Angle (ATRA) are indirect length measures using the resting angle of the ankle. Copenhagen Achilles Length Measure (CALM) is a direct ultrasound measure. The purpose of this study was to examine the construct validity of ATLM and ATRA using CALM as gold standard.
Methods: As the three measurements measure slightly different constructs and have different scales a direct comparison was not possible. Instead a mixed linear regression model was performed investigating the three models: CALM-ATRA, CALMATLM and ATRA-ATLM.
Results: 130 patients were available for analysis. All three regression models demonstrated a statistically significant ($p < 0.01$) linear relationship and acceptable certainty of the estimates.
Conclusion: ATRA and ATLM were found to have acceptable construct validity when using CALM as gold standard for assessing tendon elongation after an Achilles tendon rupture.

1. Introduction

Patient suffering an Achilles tendon rupture encounter deficits many years post injury [1,2]. A frequent complication is elongation of the tendon, which is described to correlate to reduced calf muscle strength and reduced functional outcome [3–5]. It has been hypothesized that the key to optimize the treatment after an acute Achilles tendon rupture is to reduce tendon elongation [6].

The elongation of the tendon is an ongoing process that has been described to continue until 3–4 months post injury [5,7–9] and in one study until 6 months [6]. Interestingly, the tendon seems to elongate in both operatively and non-operatively treated patients [4,10]. In order to accurately study the phenomena, it is essential to have accurate and reliable measurements of tendon length that can follow elongation during rehabilitation. Several methods to measure elongation of the Achilles tendon after rupture have been described.

A clinical measure used to evaluate tendon elongation is the Matles test [11] but used in a modified way. Matles test is originally a diagnostic test where the position of the patients' feet is compared while the patient lays prone with knees flexed 90 degrees. If the injured foot is hanging down in dorsiflexed position compared to the other foot, the tendon is deemed to be ruptured. This comparison of the feet's position has been used modified during the rehabilitation phase – if the injured foot is more dorsiflexed than the other, the tendon of the injured foot is elongated.

With the modified Matles test as starting point, Achilles Tendon Resting Angle (ATRA) [12] and Achilles Tendon Length Measure (ATLM) [13] were developed. In both tests the patient lays prone with knees flexed 90 degrees. ATRA use a goniometer to measure the angle in the ankle joint and ATLM measure the distance from

Abbreviations: ATRA, Achilles Tendon Resting Angle; ATLM, Achilles Tendon Length Measure; CALM, Copenhagen Achilles Length Measure; CI, Confidence interval; ICC, Intra class correlation; MDC, Minimal detectable change; SEM, Standard error of measurement; MRI, Magnetic Resonance Imaging.

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the foot to the examination couch. Both measurements compare the injured side with the non-injured side and the difference between the sides is an indirect measure of Achilles tendon elongation. Thereby, ATRA provides a result in degrees and ATLM in centimeters.

A way to measure tendon elongation directly in both clinical practice and within research is to use an ultrasound examination [14,15]. The ultrasound examination that has shown best reliability is the Copenhagen Achilles Length Measure (CALM) [16]. While performing CALM, the proximal (medial gastrocnemius muscle tendon junction) and distal (tendon insertion at calcaneus) landmarks of the Achilles tendon is localised with ultrasound and the distance between landmarks is measured with at tape measure. CALM provide a result in millimetres and has showed good validity and acceptable reliability [14,17].

The purpose of this study was to examine the construct validity of ATLM and ATRA using CALM as gold standard among patients treated non-surgically after an Achilles tendon rupture. Our hypothesis was that the relation between ATLM/ATRA and CALM could be described linearly. Secondly, we wanted to describe the change of elongation over time, the first year after an Achilles tendon rupture.

2. Methods

This is a validity study using prospectively collected data. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) [18] guideline was followed.

2.1. Patients

130 patients, treated non-surgical, enrolled in a randomised controlled trial [19] were available for the present study. Inclusion criteria were: age 18–70, able to attend follow up examinations, able to speak and understand Danish, and written informed consent. Exclusions criteria were: previous Achilles tendon rupture or operation in the Achilles tendon, a distance less than 1 cm from the rupture to calcaneus, treatment with fluoroquinolones or a cortisone injection within the last six months, arterial insufficiency in the legs, terminal or critical medical illness.

The patients received oral and written information of the project. Permission were obtained from the Danish Data Protection Agency and the Ethical Review Board of the Capital Region of Denmark (identifier: H-4-2013-176).

2.2. Rehabilitation programme

All patients were treated non-surgically. They had a circular below the knee cast in equinus position for the first 2 weeks followed by a DJO Aircast Walker from week 3–8 with gradual removal of heel wedges. 2 wedges each providing $1^1/_2$ cm heel lift were applied in week 3–4, 1 wedge in week 5–6 and no wedge in week 7–8. Full weight bearing on the injured limb was allowed from beginning of the third week. All patients followed a standardised physiotherapy-led exercise program twice weekly from week 8 to 16 after their Achilles tendon rupture.

2.3. Measurements

2.3.1. Achilles Tendon Length Measure (ATLM)

ATLM was measured as described by Hansen et al. [13]. ATLM was measured with the patient laying in prone position with the knees flexed to 90°. The point of reference (centre of the fifth metatarsal head) was palpated and marked with a pen. The ATLM was measured as the distance in centimetres between the head of the fifth metatarsal and the underlay (Fig. 1). The difference in the centimetres between non-injured and injured side is an indirect measurement of tendon elongation. ATLM has shown to have an acceptable relative reliability (Intra class correlation 0.58–0.79) with quite large measurement error (Minimal detectable change (MDC) 1.1–2.2 cm, 61–76 MDC%) on an individual level. Meanwhile, the measurement error on group level (Standard error of measurement, SEM) was acceptable (0.4−0.8 cm, 22.2–27.6 SEM%) [17].

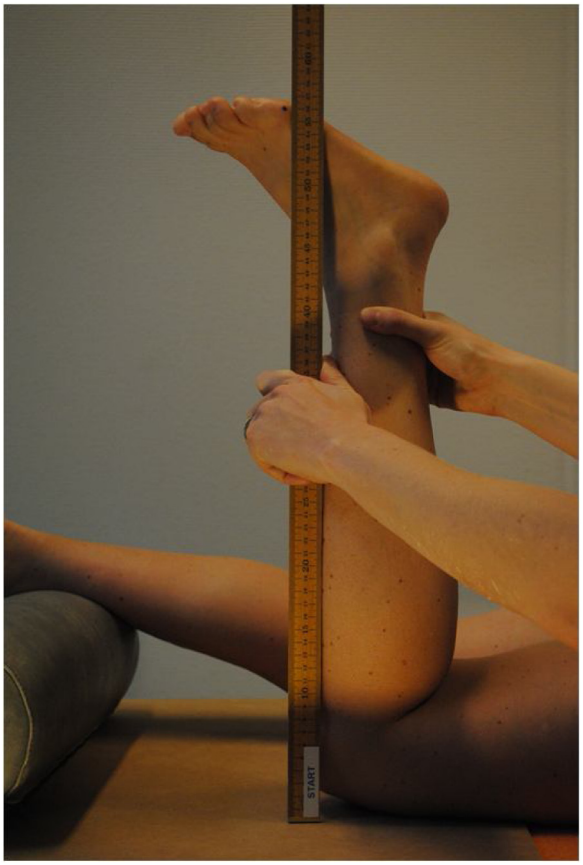

Fig. 1. Achilles Tendon Length Measure (ATLM) where the distance from the centre of the fifth metatarsal head and the underlay is measured with a ruler.

2.3.2. Achilles Tendon Resting Angle (ATRA)

The ATRA [12] was measured as described by Hansen et al. [13] with the same starting position as for ATLM. The point of references was palpated and marked with a pen; the fibular head, the distal tip of the lateral malleolus and the centre of the fifth metatarsal head). The goniometer was placed against the marks (Fig. 2) and the acute angle was measured. The difference in degrees between the non-injured and the injured side is an indirect measurement of tendon elongation. ATRA has shown to have an excellent (ICC $\geq$ 0.75) relative reliability with acceptable measurement error on group level (1.1–2.3°, 6.9–14.4SEM%) and slight high on an individual level (3.1–6.4° 19–40 MDC%) [17].

2.3.3. Copenhagen Achilles Length Measure (CALM)

CALM was performed as described by Barfod et al. [14]. CALM was measured with the patient laying in prone position with knee flexed 10°. Landmarks were identified during longitudinal scan and marked with a pen. The distal landmark was the posterior and most superior part of the calcaneus in the midline. The proximal landmark was the distal tip of the medial gastrocnemius head. The distance between the landmarks was measured with a tape measure. The difference in millimetres between non-injured and

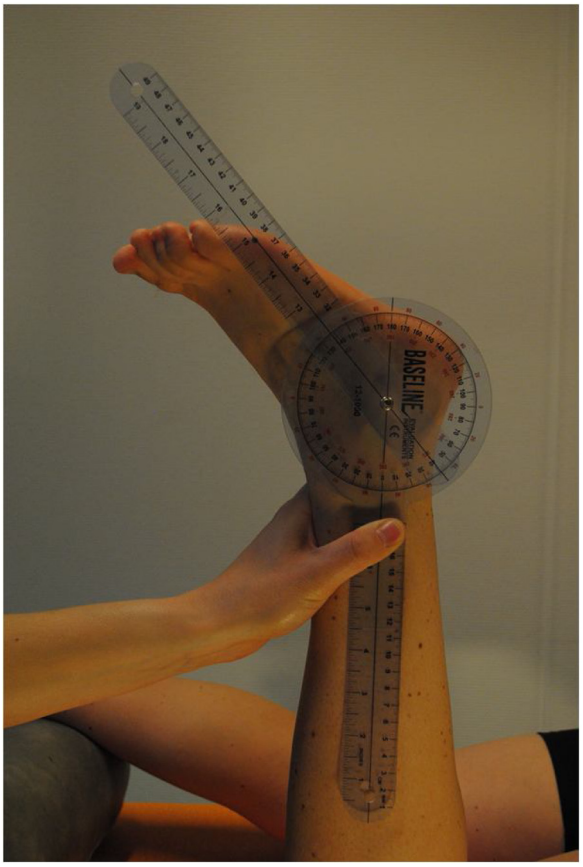

Fig. 2. Achilles Tendon Resting Angle (ATRA) where the resting angle in the ankle joint is measured with a goniometer.

injured side is a direct measurement of tendon elongation (Fig. 3). CALM has shown to have an excellent (ICC $\geq$ 0.75) relative reliability with acceptable measurement error on group level (0.3–0.6 cm,18–29 SEM%), but quite large measurement error (0.8–1.7 cm, 47–81 MDC%) on an individual level [17].

2.4. Testing procedure

Measurements were perfomed 2, 4, 6 and 12 months after injury. The measurements were performed in the same order every time; ATLM followed by ATRA and CALM at last. Three different physiotherpist, trained and confident with the assessment techniques, perfomed the measurements.

2.5. Statistical analysis

The sample size was based on the number of patients included in the randomized controlled trial, from where the data were gathered.

The study was performed as a validity study. As the three measurements used in the analysis were longitudinal/dependent, measure slightly different constructs and have different scales a direct comparison was not possible. Instead a mixed linear regression model was chosen to investigate how changes on the different scales were associated. Three models were investigated (dependent/independent); CALM/ATRA, CALM/ATLM and ATRA/ATLM. Beside measurements of elongation the following independent variables were included in the models: time after injury, age and gender. A residual plot was used to validate the model. All available measurements were included in the regression analysis. No imputation of missing values was performed. This analysis was made in statistical programme R 3.6.0 [20]. The level of significance was set at p less than 0.05.

Change of elongation over time were estimated with mean and 95% confidence interval at the different time points using SPSS version 19.0 (SPSS Inc, 233 S Wacker Dr, 11th Floor, 156 Chicago, IL 60606). Only patients with complete dataset were included in this analysis.

3. Results

130 patients were available for the regression analysis. All patients had data from minimum two follow up time-points, why all collected data could be included in the analysis and no patients were excluded due to missing data. The mean age was 41.8 years (SD 10.5, [range 20–70]), 107 male and 23 women.

The regression model demonstrated a linear relationship between the three measurements, which were statistically significant in all models ($p < 0.01$). For each degree ATRA increased, CALM increased with 0.39 mm (CI 0.12;0.66) and based on 449 observations. For each cm ATLM increased, CALM increased with 1.65 mm (CI 0.65;2.65) and based on 449 observations. For each cm ATLM increased, ATRA increased with 1.57 degrees (CI 1.26;1.89) and based on 497 observations.

For the analysis of the development of elongation over time only patients with complete dataset (n = 84) were included. The mean age was 42.4 years (SD 11.2, range 20–70), 66 male and 18 females.

All three measurements showed the largest tendon elongation at the 2 months follow up which decreased over the first year (Fig. 4). Elongation measured with CALM was 20.4 mm (CI 17.2;23.5) at 2 months and 15.6 mm (CI 12.7;18.5) at 12 months. Elongation measured with ATRA was 14.5° (CI 13.3;15.8) at 2 months and 8.1° (CI 7.1;9.1) at 12 months. Elongation measured with ATLM was 2.8 cm (CI 2.5;3.1) at 2 months and 1.5 cm (CI 1.3;1.7) at 12 months.

4. Discussion

The primary finding from this validity study was that ATRA and ATLM was statistically significant correlated to CALM with acceptable confidence intervals. The confidence intervals can be

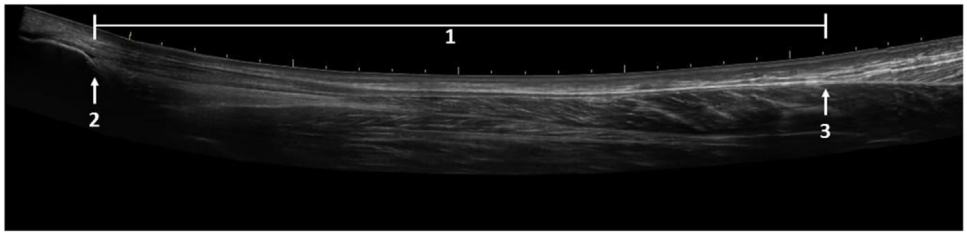

Fig. 3. Copenhagen Achilles Length Measure (CALM). (1) The distance between the landmarks, (2) Distal landmark (the posterior and most superior part of the calcaneus in the midline), (3) Proximal landmark (distal tip of the medial gastrocnemius head).

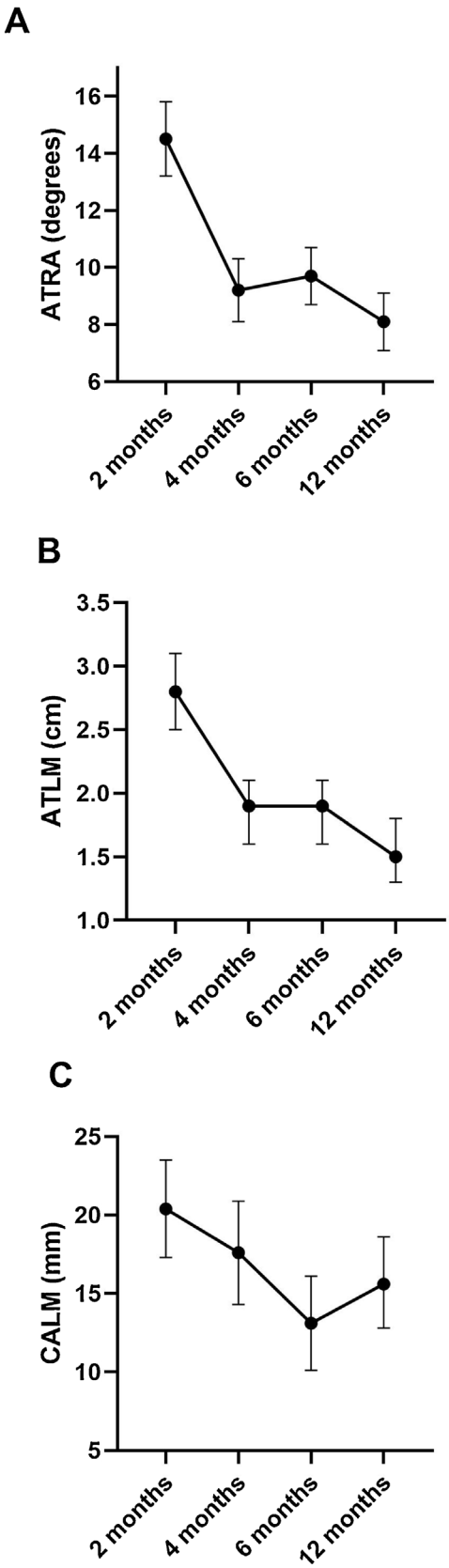

Fig. 4. Change in elongation from 2 to 12 months measured with (A) Achilles Tendon Resting Angle (ATRA) measured in degrees, (B) Achilles Tendon Length Measure (ATLM) measured in centimeters (cm), (C) Copenhagen Achilles Length Measure (CALM) measured in millimeters (mm). The distance measured with ATLM is not directly comparable with the distance measured with CALM.

used to evaluate the degree of uncertainty of the estimate. For the CALM/ATRA model: if ATRA increases by 10 degrees, CALM increase 3.9 mm, plus/minus 2.7 mm. For the CALM/ATLM model: if ATLM increase by 1 cm, CALM increased by 1.6 mm, plus/minus 1 mm. When comparing the width of the confidence interval with the estimate, the CALM/ATRA model's confidence interval is plus/minus 69% of the estimate and for the CALM/ATLM model, the confidence interval represents plus/minus 63% of the estimate. The width of these confidence intervals is comparable and we consider them as clinical acceptable.

4.1. Test of construct validity between measures with different constructs

The three measurements are measuring different constructs; ATRA measure an angle in the ankle joint, ATLM a distance from the foot down to the underlay and CALM the distance from the distal tip of the medial gastrocnemius muscle to the calcaneus. The correlation of ATRA and ATLM to CALM indicate that even though they measure different constructs, they describe the same overall construct, tendon elongation. Indirect for ATRA and ATLM and directly for CALM.

The correlations of ATRA and ATLM to CALM are clinically reasonable. Costa et al. [21] concluded that the Achilles tendon is the anatomical structure limiting ankle dorsiflexion. Meaning, that in prone position and 90 degrees bend knees the position of the ankle joint is determined by the length of the Achilles tendon.

The present study demonstrates a linear relationship between the three measurements, but the study does not establish a factor allowing conversion of the ATRA and ATLM into a direct measure of tendon elongation. We suggest using ATRA and ATLM as a screening tool for tendon elongation and to use CALM or another direct measure if in need of a direct measurement. Furthermore, ATRA and ATLM are alternatives for clinicians who do not have access to direct measurements of tendon elongation.

The results of our study are in line with the correlation that Zellers et al. found [22] in their validity test of ATRA. They investigated 42 tendons treated both with (n = 31) and without (n = 11) surgery. Although their mean time after injury varied (18.2 months, SD = 35.9, range 1–167), their mean elongation, measured using extended field of view ultrasound imaging, for all patients was 16 mm, which is close to our mean elongation at 12 months (15.6 mm). Accordingly, even though only patients treated non-surgically were included in the present study, the effect of surgical or non-surgical treatment on validity appears to be limited.

4.2. Tendon elongation

Interestingly, the patients in our study showed tendon elongation to decrease from 2 months to 12 months after injury. Previous studies have shown the elongation to increase until 3 months post injury [3,5,7–9]. Both when measured as the change of tendon over time [5,7,8], and as the difference in tendon length between injured and non-injured side [3,4,9]. These differences might be explained by the fact that these studies have had patients treated with surgery, except one group of patients in the study by Schepull et al. [7], whereas the patients in our study were treated non-surgical. Nonetheless, the degree of tendon elongation 12 months post-injury is similar when comparing values for ultrasound examinations with those of Zellers [22] (16 mm compared to 15.6 mm in the present study) and for ATRA with those of Carmont ([9] (6 degrees compared to 8.1 degrees in the present study). The reason for tendon elongation is not established. It might be a consequence of limited spontaneous healing due to hypocellularity and hypovascularization in the Achilles tendon [23]. Our finding, having the elongation to decrease from 2 to 12

months, could be due to a reorganisation of the triceps surae muscle-tendon complex. Svensson et al. [24] suggest that the triceps muscle compensates for an elongated tendon by reduction of fascicle length.

4.3. Strengths and limitations

The strength of the present study is the large sample size, the systematic statistical method and the validation against a direct measurement of elongation (CALM). Furthermore, the sample is representative to the average patient acquiring an Achilles tendon rupture regarding age and gender [25,26]. On the other hand, the role of CALM as gold standard for measurement of elongation can be discussed. Elongation measured with Magnetic Resonance Imaging (MRI) has shown slightly better reliability when measured on non-injured test persons [14] and one could argue that the use of MRI as gold standard would be preferable.

5. Conclusion

ATRA and ATLM have acceptable construct validity for assessing tendon elongation after an Achilles tendon rupture when using CALM as gold standard. One measure cannot be translated directly into another. Still, we suggest using ATRA and ATLM as a screening tool for tendon elongation and to use CALM or another direct measure if need of a direct measurement.

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Conflict of interest

The authors have no financial conflicts of interest. Academically, the authors declare to be the inventors of CALM.

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Achilles tendon gait dynamics after rupture: A three-armed randomized controlled trial comparing an individualized treatment algorithm vs. operative or non-operative treatment.

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Trials registry

This trial was registered at ClinicalTrials.gov the 1st of June 2018 (NCT03543943). No changes to the study design have been made.

Ethics approval

The protocol, as well as the patient information and declaration of consent, was approved by the National Committee on Health Research Ethics (journal number: 1-10-72-428-17).

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Competing interests

None declared.

ABSTRACT

Objective: Individual treatment selection has been proposed as the key to optimized treatment for patients with an Achilles tendon rupture. The purpose of the present study was to determine if gait dynamics, Achilles tendon elongation, and patient-reported outcome measures differ between patients using the individualized treatment algorithm Copenhagen Achilles Rupture Treatment Algorithm (CARTA) and patients treated as usual (operatively or non-operatively by default).

Design: A three-armed randomized controlled trial.

Methods: The patients were randomized in a 1:1:1 order to one of three parallel groups: 1) intervention group: participants treated according to the individualized ultrasound based treatment algorithm CARTA, 2) control group: participants treated non-operatively, and 3) control group: participants treated operatively. Patients aged 18-65 years were eligible for inclusion. The primary outcome was ankle peak power during push off during walking at 12 months, measured in a 3D gait laboratory. Secondary outcomes were ankle plantar flexor moment, peak dorsal flexion during stance, tendon elongation and Achilles tendon Total Rupture Score (ATRS). Analysis was conducted as intention-to-treat.

Results: One hundred and fifty-six patients were assessed for eligibility from June 2018 to September 2019. Twenty-one were allocated to the intervention group, and 20 and 19 to the two control groups. The results indicated no statistically significant differences between the intervention group and the two control groups at six- and 12-month follow-ups.

Conclusion: Patients receiving individualized treatment using CARTA did not demonstrate less affected gait dynamics, less tendon elongation, or a higher ATRS than patients treated operatively or non-operatively by default.

Key-words: Achilles tendon rupture, gait dynamics, tendon elongation, individualized treatment, ultrasound

INTRODUCTION

The average patient sustaining an acute Achilles tendon rupture is male around 40 years of age[8] with a clear goal of returning to pre-injury sports and work.[19] The results are not satisfactory, with a low rate of patients returning to sports[6,19] and patients experience physical limitations for several years .[14]

Fully recovered gait pattern is considered a basic goal for all patients. Unfortunately, two to five years after injury, biomechanical deficits during walking with increased dorsiflexion and decreased plantar flexor power and work, are common.[26,28] This might be due to persistent tendon elongation resulting in reduced force production in the end range of plantar flexion during push off.[20,29]

The differences between operative and non-operative treatment have been frequently discussed.[9,22] A systematic review and meta-analysis from 2019 concluded that operative treatment reduces the risk of re-rupture, but is associated with a higher risk of complications.[22] However, re-rupture rates are low and differences between groups are small. The study proposed that decision making of how to treat an acute Achilles tendon rupture should be based on patient specific factors.[22]

Individual treatment selection algorithms, based on the morphology of the rupture, have also been proposed[1,15], but their efficacy have never been evaluated. In that view, the newly-developed Copenhagen Achilles Rupture Treatment Algorithm (CARTA)[13], an individualized treatment algorithm based on the validated ultrasonographic Copenhagen Achilles Length Measure (CALM)[3,12] might be of relevance. CARTA is based on a combination of tendon overlap inspired by Amlang's Classification system[1] and tendon elongation measured with CALM.[12] It has been shown tendon elongation of more than 7% in the subacute phase after rupture increases the risk of more than 10% elongation at one year follow up (manuscript in press)

The hypothesis was that patients treated according to CARTA would have a less-affected walking dynamics, less tendon elongation, and a higher score within the patient-reported outcome measures, than patients in the control groups.

METHODS

The trial was performed as a three-armed randomized controlled trial with the patients randomized in a 1:1:1 order to one of three parallel groups. The patients included are the first 60 patients included at Hvidovre hospital in an on-going national trial in which 300 patients will be included.[13] The trial protocol was developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), and the Consolidated Standards of Reporting Trials (CONSORT) guidelines and checklists.[7,18]

The protocol, as well as the patient information and declaration of consent, was approved by the National Committee on Health Research Ethics (journal number: 1-10-72-428-17). Informed consent was obtained, and the rights of participants were protected.

This trial was registered at ClinicalTrials.gov the 1st of June 2018 (NCT03543943) and the study protocol published in *TRIALS Journal.*[13] No changes to the study design have been made.

There were no patients involved in the design or in the conduct of the study. Still, five patients participated in a semi-structured interview investigating how best to convey the study results to the participants in the study.

Study participants

Patients treated for an acute Achilles tendon rupture at Copenhagen University Hospital Amager-Hvidovre were assed for eligibility. Inclusion criteria: 18-65 years, an appointment in the outpatient clinic within four days, a total Achilles tendon rupture, initial treatment with split

plaster cast with the ankle in maximal plantar flexion started within 24 hours, possibility of attending post-examinations, ability to speak and understand Danish and to give informed consent. Exclusion criterion: a rupture of the Achilles tendon either at the insertion on the calcaneus or at the musculotendinous junction. Additional exclusion criteria are reported in the protocol paper.[13] Patients were given written and verbal information. Those who did not want to participate were treated non-operatively according to the department's guidelines.

Treatment

The diagnosis was set in the emergency room based on the patient history and a clinical examination (calf-squeeze test[25], Matles test[17] and palpable defect in the Achilles tendon). A split plaster cast with the ankle in maximum plantar flexion was applied, no weightbearing allowed.

Within four days after rupture, the patients attended the outpatient clinic to conduct the randomization into one of three groups:

1. Intervention group: participants treated according to CARTA.
2. Control group: participants treated non-operatively.
3. Control group: participants treated operatively.

The intervention

In the intervention group patients were treated according to the individualised treatment algorithm. CARTA was based on two ultrasonographic examinations conducted within 4 days after injury (**FIGURE 1,** supplementary material). A detailed description of CARTA is found in the protocol paper.[13]

Firstly, the degree of overlap of the ruptured tendon stumps was examined by looking at the cross-sectional area. If less than 25% tendon fibers at the rupture site, the overlap was considered minimal and the patient was recommended for operative treatment. If more than 25% fibers, the overlap was considered substantial and the patient was scanned for elongation.

Secondly, tendon elongation was measured using CALM.[12] Both legs were examined and the difference between the sides was calculated as the elongation and was given as a percentage of the length of the non-injured tendon. Patients with up to 7% elongation were treated non-operatively and patients with 7% or more were treated operatively.

Non-operative treatment

The patients randomized to the non-operative control group or to the intervention group with the decision to be treated non-operatively, were treated with a circular below-the knee cast with the ankle in maximal plantar flexion and no weight-bearing. After three weeks the cast was replaced by a functional brace with three heel wedges, promoting 20 degrees of plantarflexion over the ankle. A wedge was removed after two and four weeks and the orthosis after six weeks. Partial weight bearing was allowed from week four to seven and full weight bearing from week eight onwards. The brace was to be kept on at all times except during bathing if the patient was seated and did not bear weight on the foot[13]. In weeks 10 to 13, just after removal of the orthosis, the patients were instructed to perform a home exercise program twice daily, and from week 14 the patients started rehabilitation in the municipality. Please visit the protocol paper for a full description and rehabilitation program[13].

Operative treatment

Patients randomized to the operative control group or the intervention group with the decision to be treated operatively were operated on within 14 days after rupture. Please refer to the protocol paper for a description of the operation technique.[13] After the operation, patients were treated exactly like the non-operatively treated patients with a circular below-the knee cast for three weeks and an orthosis for six weeks followed by physiotherapy led exercises.

Outcomes

The primary outcome was peak ankle plantarflexor power during push off at 12 months; this was the maximal power produced by the plantar flexors during the push off phase. Gait analysis was performed as previously described by Speedtsberg et al[26] using a Vicon Motion Systems.[24] Data were subsequently calculated using the inherent software (Nexus 2.9.1; Vicon Motion Systems, Oxford, UK) and outcome parameters were extracted using custom-made Matlab scripts (MATLAB 9.0.0,R2016; MathWorks Inc.,Natick, MA).

Secondary outcomes were peak ankle plantarflexor power during push off at six months, peak ankle plantarflexor moment at six and 12 months, and peak dorsal flexion during stance phase at six and 12 months.

Tendon elongation measured with ultrasound using the CALM at six and 12 months was also a secondary outcome.[3,12]

The patient-reported outcome measure used was the Achilles tendon Total Rupture Score (ATRS, ranging from 0-100, where 100 expresses no symptoms), which was developed to assess symptoms and physical activity after treatment of an acute Achilles tendon rupture.[11,21]

Randomization

Randomization was computer-based and conducted through a web-based database hosted by Procordo, Copenhagen, Denmark.[13] The allocation key was only accessible by Procordo.

Blinding

Due to the nature of the intervention, it was not possible to blind the patient. Inclusion, randomization, and follow-up were performed by the lead investigator. The surgeons performing the operative treatment were blinded to treatment arm (individualized or surgical). Follow-up was not fully blinded, as the lead investigator performed both randomization and follow up, but to blind the investigator for operative and non-operative treatment, the patients had a piece of tape placed over the Achilles region on the injured leg during the gait analysis. Data were blinded while performing the statistical analyses.

Statistics

As of the planning of this study, to our knowledge, no measurements were available for the primary outcome to make a reliable sample size calculation. Therefore, sample size was based on what was logistically possible to complete within the time plan. Hence, results of this study should be considered exploratory; that is, indicating but not confirmatory of any effect.

Demographic parameters were presented for each treatment group with mean and standard deviation (SD) or median and interquartile range (IQR) for continuous variables, depending on the distribution of data, and with frequencies and percentages for categorical variables.

The non-injured side was used as a reference for gait biomechanical outcomes as well as for tendon elongation. The difference between the injured and non-injured side for walking was used as an expression of affected gait. The outcomes expressed in power (watt/ body mass)

and moment (Newton meter/body mass) were calculated as the percentual deficit (difference between injured and non-injured side/value for non-injured side*100).

The primary outcome, difference in peak ankle power during push-off at 12 months, was tested with use of ANCOVA. Tests were made for the comparison intervention group vs. operative control group, and intervention group vs. non-operative control group. Possible confounding variables (sex, age, BMI, ATRS pre-injury and pre-injury activity level, tendon elongation) were evaluated by comparison of intervention vs. control groups estimates from models with, and without, the specific confounder. If a relevant change was observed, the variable was included as a confounder.

The secondary outcomes, gait analysis at six and 12 months as well as tendon elongation at six and 12 months, and ATRS, were analyzed with the similar ANCOVA model as for the primary outcome, with relevant confounders evaluated for each model. The analyses on ATRS were done both for the full score (range) and for items 6 to 10 separately since they represent different physical tasks.

All analysis was done as intention to treat (ITT). Additionally, the analysis for the primary outcome was also conducted as per protocol analysis.

Missing data was imputed by multiple imputation; 100 imputations were performed, with imputation models based on available variables.

Additionally, a sub-analysis for the primary outcome was done by only including patients measured within the time limit (plus/minus one month) in the model, to evaluate possible bias introduced from prolonged follow-up time.

Re-rupture rate was noted. The precise definition of a re-rupture contra a re-injury is somewhat subjective and up to the individual clinician. Therefore, all re-injuries that led to a change and a re-start of the treatment plan were considered a re-rupture.

Estimates were presented with 95% confidence intervals (CI). All analysis was done in R 3.6.0[23] with the mice package[5] used for multiple imputation. A p-value of less than 0.05 was considered statistically significant.

RESULTS

One hundred and fifty-six patients were assessed for eligibility from June 2018 to September 2019 (**FIGURE 2**). The baseline data of the population is shown in **TABLE 1**.

One patient was lost to follow-up and four patients were not able to perform the gait analysis, leaving 55 patients available for the 12-month follow-up for the primary outcome (**FIGURE 2**). All 21 patients in the intervention group adhered to the assigned treatment. Of the 20 patients in the non-operative control group, 19 adhered to the assigned treatment; one patient fell on his bare foot when standing up without the walker and sustained a re-rupture treated operatively. Of the 19 patients in the operative control groups, 18 adhered to the assigned treatment; one patient started bicycling and sustained a re-rupture treated with a cast for two weeks and a functional brace for four weeks.

The use of the CARTA algorithm led to 14 of 21 patients in the intervention group being treated operatively and seven patients non-operatively. If the CARTA algorithm had been applied in the operative control group, 16 patients would have been treated operatively and three non-operatively. In the non-operative control group, 14 patients would have been treated operatively and six non-operatively.

Primary outcome

The average peak ankle plantarflexor power during push off deficit was 14% (CI=7.20:21.4) p=<0.001 at six months and reduced to 7% (CI=0.9:13.6) p= 0.027 at 12 months for the intervention group, with no statistically significant differences in comparison with the control

groups (at 12 months: intervention group vs. operative control group -0.39% (-10.48:9.70) p=0.939, intervention group vs. non-operative control group 4.83% (-3.67:13.33) p=0.259) (**FIGURE 3**).The intention to treat and per protocol analysis did not show any statistically significant differences. Neither did the sensitivity analysis.

The following variables were found to contribute confounding effect to the models: ATRS pre-injury, pre-injury activity level, age, BMI, sex, tendon elongation and time to follow-up. However, inclusion of these confounders did not lead to changes in the statistical or clinical interpretation of the models compared to the unadjusted models. Because of this, results are reported from the unadjusted models.

Secondary outcomes

Regarding the secondary outcomes (**FIGURE 3-5**), no statistically significant or clinically relevant differences between the groups were found. The between group differences in peak ankle plantarflexor moment deficit at 12 months were: intervention group vs. operative control group 0.07% (-4.66:4.79) p=0.977, intervention group vs. non-operative control group 1.20% (-3.10:5.51) p=0.577. Corresponding values for the other secondary outcomes at 12 months were: peak dorsiflexion angle during stance phase 0.97 degrees (-1.23:3.16) p=0.378, 0.34 degrees (-1.59:2.28) p= 0.724, tendon elongation 0.35 mm (-8.84:9.53) p= 0.940, -0.61 mm (-9.51:8.29) p=0.891 and ATRS score -5.64 point (-20.36:9.08) p= 0.445, -3.02 (-16.99: 10.95) p=0.666.

Regarding differences between injured and non-injured side for the intervention group, statistically significant differences among the secondary outcomes were found in peak ankle plantarflexor moment at 6 months (-5.72% (-11.12:-0.31) p=0.039), in tendon elongation both at 6 (17.71 mm (12.36:23.07) p=<0.001) and 12 months (19.41 mm (13.00:25.83) p=<0.001), and in ATRS at 12 months (73.57 points (63.81:83.33) p=<0.001)

In total, five patients experienced a re-rupture. None of them were enrolled in the intervention group; four were assigned to the non-operative group and one to the operative group. Within the four patients assigned to the non-operative group, three of them would have been treated operatively if treatment selection had been made using CARTA.

DISCUSSION

The most important finding of the study was that individualized treatment selection for operative vs non-operative treatment based on CARTA does not seem to result in less affected gait dynamics, less tendon elongation, or a higher ATRS score than treating patients operatively or non-operatively by default. This is the first study evaluating an individualized treatment algorithm in a randomized controlled set-up with functional outcomes. Other algorithms have been proposed by Amlang[1] and Hutchinson et al[15] and shown promising results, but none of them have been assessed in a randomized trial.

A weakness of CARTA and potential reason for no between group differences in the present study could be that the first part of the ultrasonographic examination (tendon overlap) has not been validated. Although, the rationale of tendon overlap inspired by Amlang et al[1] is clinically reasonable. The ultrasound finding used in the treatment algorithm by Hutchinson et al[15] on the other hand, a gap of the tendon above 1 cm on passive plantar flexion is questionable since a gap is rarely present. More often, the fibers of the tendon rupture at different locations with a thinning of the tendon and a decrease of the cross-sectional area of the tendon fibers.

Additionally, gait dynamics may not be an optimal outcome for a 12-month follow-up after an Achilles tendon rupture. Dissecting the ATRS at 12 months showed high scores, meaning few problems, for activities involving walking (items 6 and 7), and lower scores when asking about the patients' ability to run and jump (items 8 and 9). Future studies should therefore consider using outcomes consisting of activities requiring higher levels of joint angular

velocity and force development, such as running and jumping, as they might be better to reveal relevant functional deficits and between-group differences.

There were statistically significant differences between the injured and non-injured side concerning all gait analysis parameters for the intervention group. The ankle plantarflexor power during push off remained statistically significantly reduced at 12 months with a deficit of 7%. The deficits in moment and power at six months have previously been described by Aufwerber et al.[2] Its clinical relevance is unknown as a clinically relevant difference has not been determined.

There were no between-group differences in tendon elongation but a statistically significant difference between injured and non-injured sides at both six and 12 months after injury, with an elongation of 17.7 and 19.4 mm found, respectively. The degree of tendon elongation[12,30] and no substantial change from six to 12 months[10] are comparable with findings in previous studies. As for power, the knowledge of a clinically relevant difference is lacking.

Time to surgery has been suggested to affect outcome with a proposed cut off for optimal outcome being 3 days after injury.[27] The mean time to surgery was 5 days, which might have affected the operatively treated patients.

Strengths within present study is the randomized controlled design following state of the art guidelines.[7,18] Furthermore, the gait analysis including 60 patients is larger than most previous study populations.[4,16,26] The limitations are the study being an exploratory study with no sample size calculation and therefore unable to give confirmatory conclusions.

CONCLUSION

Patients given individualized treatment using CARTA did not seem to result in less affected gait dynamics, less tendon elongation, or a higher ATRS than usual care. Our results suggest statistically significant deficits in ankle plantar flexor power during walking in the

injured compared to the healthy leg at 12 months after injury together with a significant tendon elongation. However, given this is an exploratory study, this must be tested with a confirmatory design.

Key Points

Findings: Individualized treatment selection for operative vs non-operative treatment based on CARTA does not seem to result in less affected gait dynamics, less tendon elongation, or a higher ATRS score than treating patients operatively or non-operatively by default.

Implications: Patients having treatment selection using CARTA seemed to have persisting deficits in gait dynamics and a significant tendon elongation 12 months after injury.

Gait dynamics as functional outcome 12 months after an Achilles tendon rupture might not be optimal and more physical demanding tasks should be evaluated.

Caution: This study has an exploratory design and requires confirmation in further prospective evaluations.

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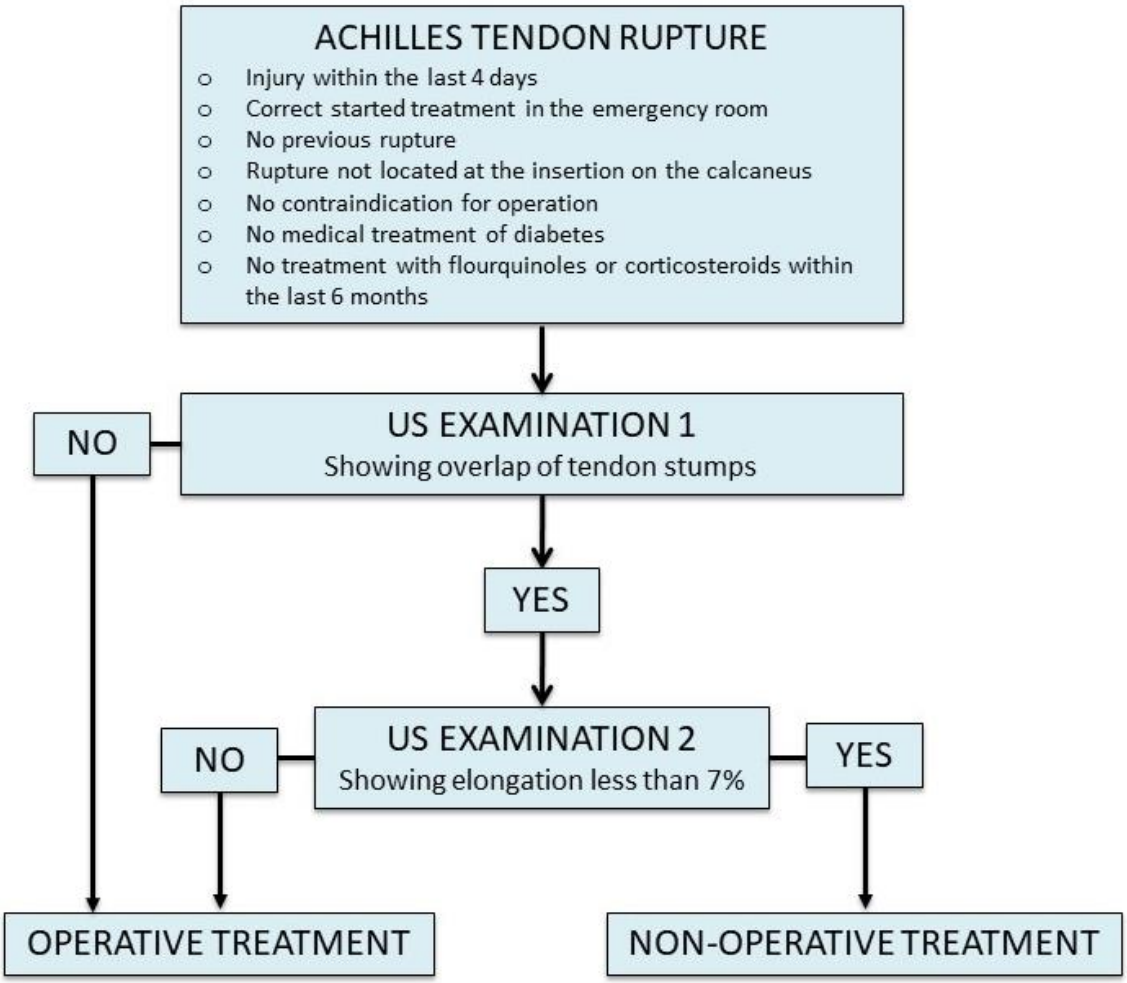
TABLE 1. Baseline data

	Randomization groups			The intervention group divided in selected treatments	
	Control group non-operative n= 20	Control group operative treatment n= 19	Intervention group n= 21	Operative treated patients n= 14	Non-operative treated patients n= 7
Age (years)	39.7 (10.1)	42.9 (8.3)	39.2 (8.8)	39.5 (8.7)	38.7 (9.8)
BMI (kg/m^2)	26.1 (2.5)	26.1 (3.6)	26.5 (3.9)	27.1 (3.0)	25.3 (3.0)
ATRS pre-injury	97.3 (4.9)	96.5 (9.4)	93.3 (13.8)	97.4 (5.3)	85.1 (21.3)
Tegner score	5.1 (2.0)	3.7 (2.2)	4.0 (1.8)	3.7 (1.7)	4.6 (2.1)
Elongation (mm)	17.2 (12.4)	24.7 (11.5)	16.4 (15.0)	23.9 (12.0)	1.6 (6.9)
Tendon overlap	15/20 (75)	13/19 (68)	10/21 (47)	3/14 (21)	7/7 (100)
Female	5/20 (25)	3/19 (16)	4/21 (19)	2/14 (14)	2/7 (28)
Injured side: left	7/20 (35)	13/19 (68)	8/21 (28)	7/14 (50)	1/7 (14)
Time to surgery (days)	-	5.1 (2.9)	5.5 (3.3)		-

Data are presented as ‘mean (SD)’ for continuous data and ‘yea/total number (percentage)’ for dichotomous data. BMI: Body mass index; ATRS: Achilles tendon Total Rupture Score.



434

435 **FIGURE 1.** The Copenhagen Achilles Rupture Treatment Algorithm (CARTA) which includes
436 two ultrasonographic (US) investigations. A detailed description of CARTA is found in the
437 protocol paper [13].

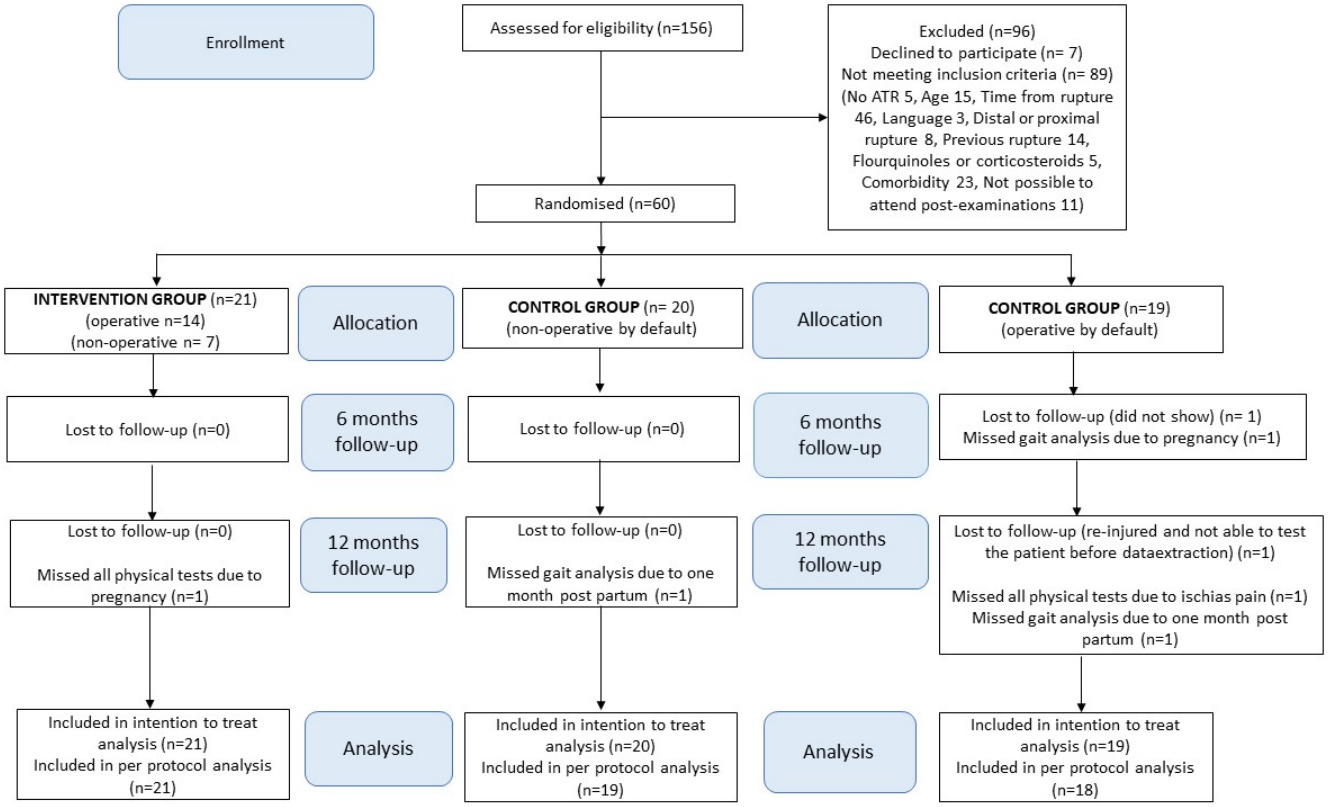
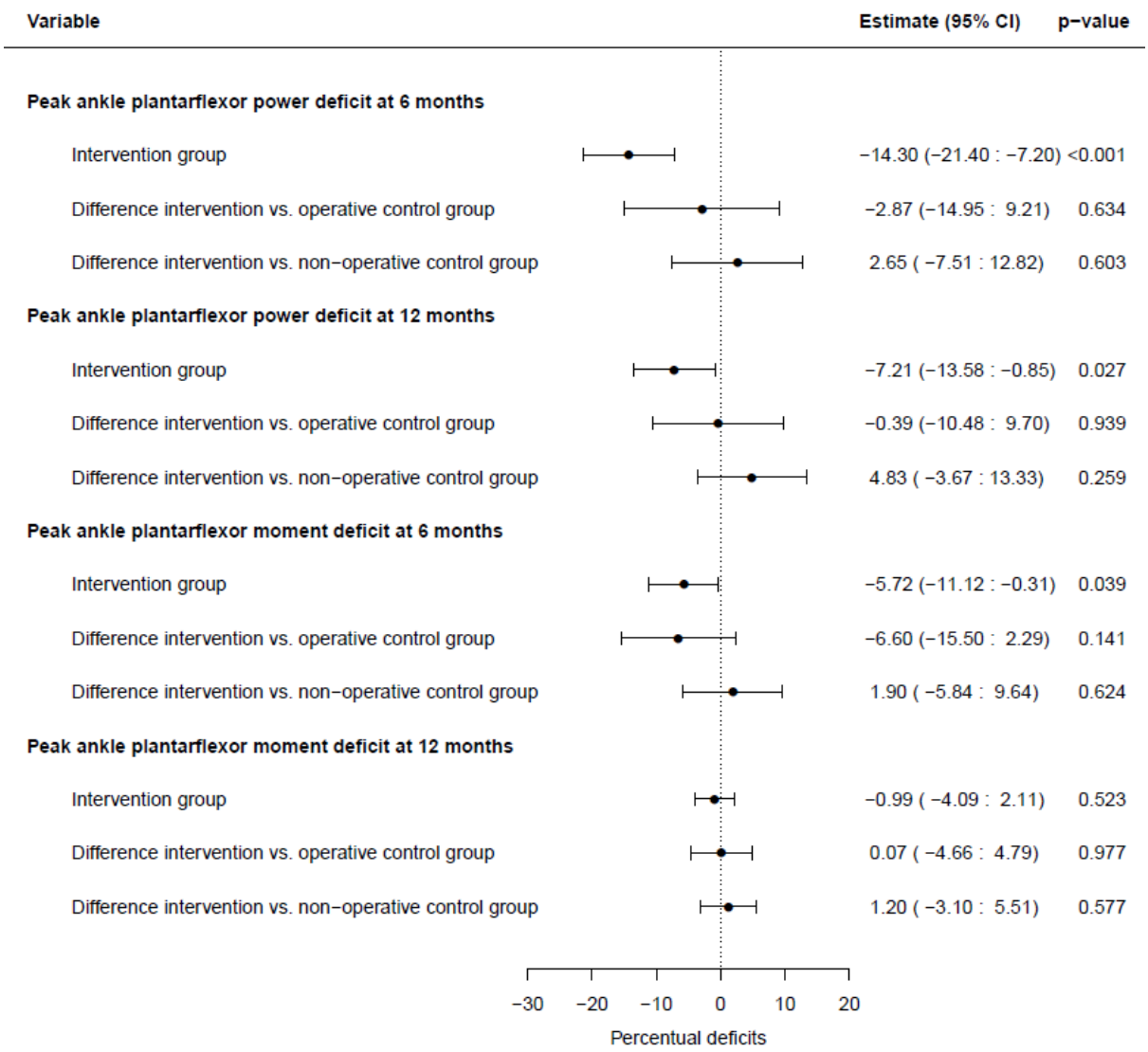


FIGURE 2. CONSORT flow diagram. The reasons for exclusion could be more than one. Missing data were imputed to allow all patients to be included in the analysis.



442

443 **FIGURE 3.** Results for peak ankle power and peak ankle plantarflexor moment at six and 12
444 months. Data are presented as percentual deficits (calculated as the difference between
445 injured and non-injured side/value for non-injured side*100), 95% CI, confidence interval.

446

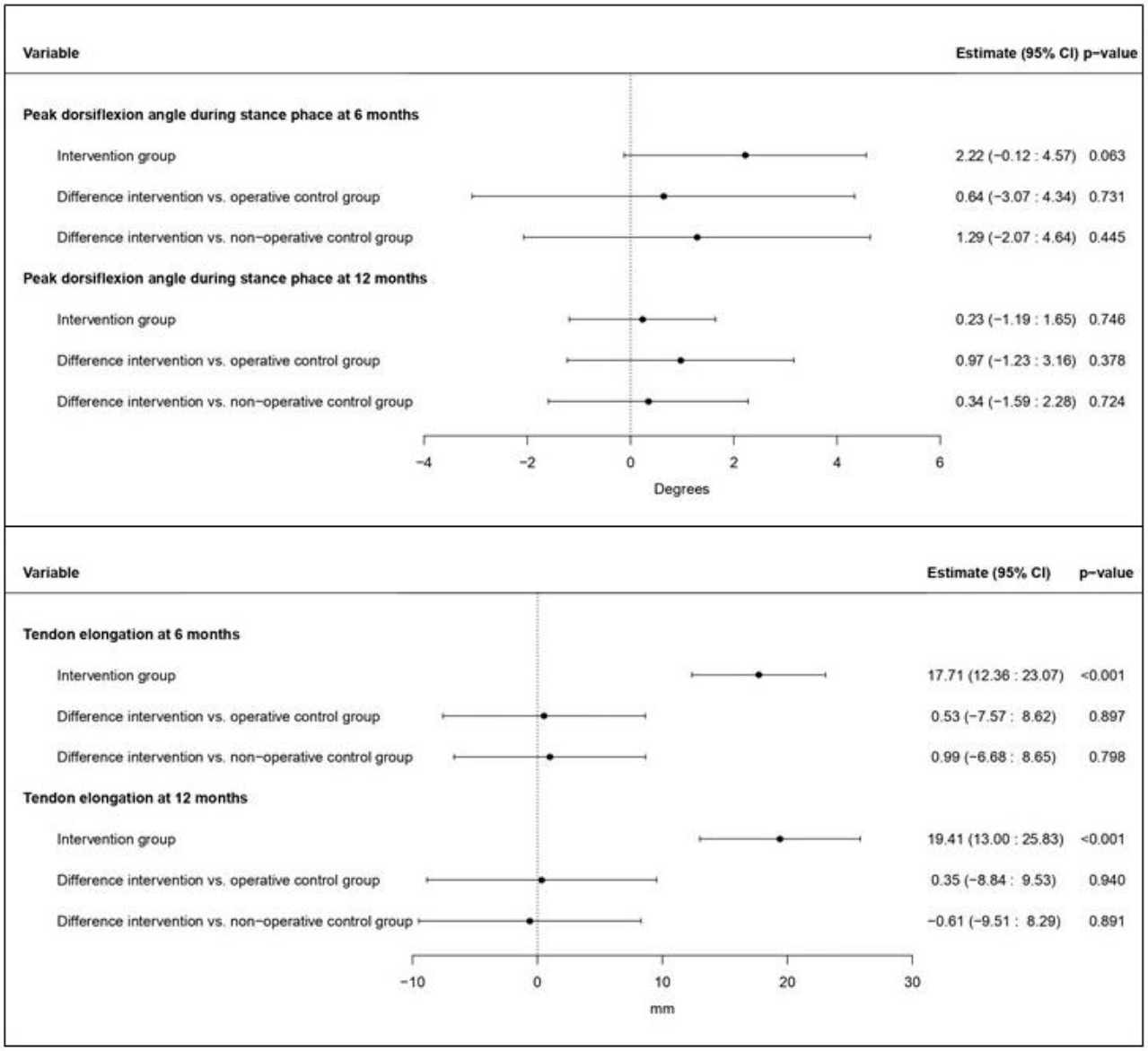


FIGURE 4. Results for peak dorsiflexion ankle during stance phase and for tendon elongation measure with CALM at six and 12 months. Data are presented as difference between injured and non-injured leg, 95% CI, confidence interval.

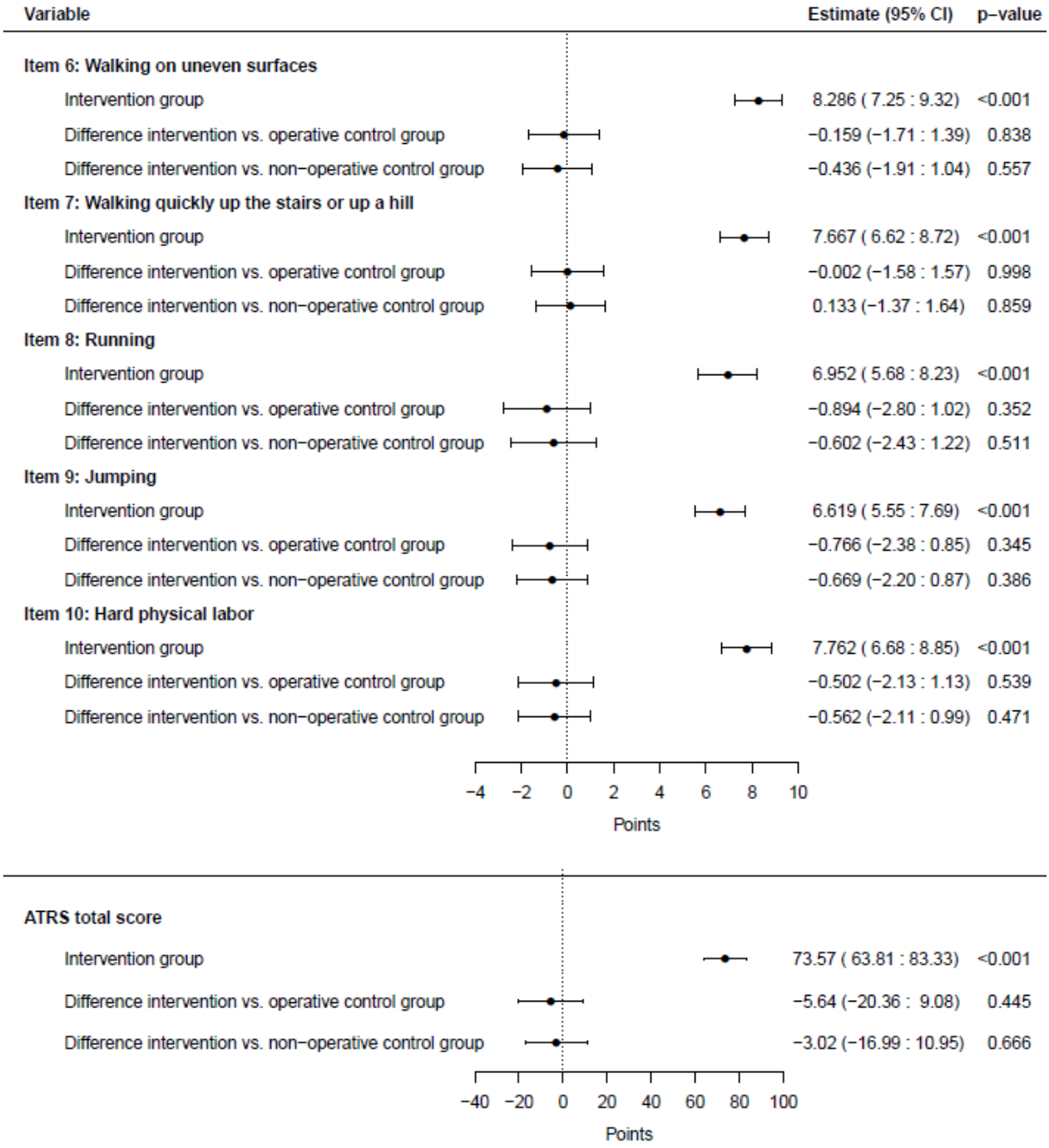


FIGURE 5. Results for ATRS at 12 months, items 6-10 and total score. ATRS, Achilles tendon Total Rupture Score, 95% CI, confidence interval.